

MEDICATED DANDRUFF - selenium sulfide shampoo

Dolgenercorp.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

Active ingredient

Selenium sulfide 1%

Purpose

Anti-Dandruff

Use for relief of itching and flaking associated with dandruff and seborrheic dermatitis and to help prevent reoccurrence

Warnings

For external use only

Ask a doctor before use if you have seborrheic dermatitis in areas other than the scalp

When using this product •do not get into eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if •condition worsens or does not improve after regular use as directed

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions •Shake well •wet hair, massage onto scalp, rinse thoroughly

•for best results use at least twice a week or as directed by a doctor

Other information for color-treated or permed hair, rinse extra thoroughly

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, xanthan gum, cellulose gum, FD+C blue no. 1, D+C red no 33, sodium citrate, sodium chloride.

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DANDRUFF

CONTROL

SHAMPOO

Selenium Sulfide

Dandruff Shampoo

•For a healthier scalp and hair

•Helps prevent flakes

11 FL OZ (325 mL)



MEDICATED DANDRUFF

selenium sulfide shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-246
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
TROLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
AMMONIUM LAURETH-3 SULFATE (UNII: 896SJ235FN)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
MENTHOL (UNII: L7T10EP3A)	

COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-246-39	.325 L in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	11/03/2011	

Labeler - Dolgencorp.LLC (068331990)

Registrant - Vi-Jon (088520668)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		088520668	manufacture