

SELENIUM SULFIDE- selenium sulfide shampoo
Sonar Products, 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.

Selenium Sulfide 1% Moisturizing Dandruff Shampoo

Drug Facts

Active Ingredient

Selenium sulfide 1%

Purpose

Antidandruff

Use

for relief of flaking and itching due to dandruff and seborrheic dermatitis and to help prevent their recurrence.

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

- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
- for 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.

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, ammonium laureth sulfate, dihydrogenated tallow phthalic acid amide, sodium chloride, cocamide DEA, dimethicone, aloe barbadensis leaf juice, titanium dioxide, hydroxypropyl methylcellulose, sodium isostearyl lactylate, DMDM hydantoin, fragrance, citric acid, sodium citrate, FD&C blue no.1 (245-067)

Manufactured By:

Sonar Products, Inc.
609 Industrial Road
Carlstadt, NJ 07072

PRINCIPAL DISPLAY PANEL - 325 mL Bottle Label

NDC 65255-409-88

SONAR PRODUCTS, INC.

**SELENIUM
SULFIDE
1% SHAMPOO**

**Moisturizing Dandruff
Shampoo**

11 Fl. Oz. (325 mL)

NDC 65255-409-88



SONAR PRODUCTS, INC.

**SELENIUM
SULFIDE
1% SHAMPOO**

**Moisturizing Dandruff
Shampoo**

11 Fl. Oz. (325 mL)

Drug Facts

Active Ingredient	Purpose
Selenium sulfide 1%.....	Antidandruff

Use for relief of flaking and itching due to dandruff and seborrheic dermatitis and to help prevent their recurrence.

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 ■ avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. ■ for 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.

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, ammonium laureth sulfate, dihydrogenated tallow phthalic acid amide, sodium chloride, cocamide DEA, dimethicone, aloe barbadensis leaf juice, titanium dioxide, hydroxypropyl methylcellulose, sodium isostearyl lactylate, DMDM hydantoin, fragrance, citric acid, sodium citrate, FD&C blue no.1 (245-067)

Manufactured By: Sonar Products, Inc.
609 Industrial Road
Carlstadt, NJ 07072



SELENIUM SULFIDE

selenium sulfide shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65255-409
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM - UNII:H6241UJ22B)	SELENIUM SULFIDE	10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DIHYDROGENATED TALLOW PHTHALIC ACID AMIDE (UNII: 1R81RPY10G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM ISOSTEAROYL LACTYLATE (UNII: 8730J0D3EV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Product Characteristics			
Color	TURQUOISE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65255-409-03	325 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part358H	02/08/2012	

Labeler - Sonar Products, Inc (104283945)

Establishment

Name	Address	ID/FEI	Business Operations
Sonar Products, Inc		104283945	MANUFACTURE(65255-409) , LABEL(65255-409)

Revised: 1/2012

Sonar Products, Inc