

CAREONE MEDICATED DANDRUFF- selenium sulfide shampoo
Retail Business Services, 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.

72476-025-03 Careone medicated Dandruff shampoo

Active Ingredient

Selenium Sulfide 1%

Purpose

Anti-dandruff, Anti-seborrheic dermatitis

Uses

for the relief of flaking and itching associated with dandruff and seborrheic dermatitis and to help prevent the chance of recurrence.

Warnings

For external use only.

Ask a doctor before use

you have seborrheic dermatitis in areas other than the scalp.

When using this Product

- Avoid contact with eyes. If contact occurs, rinse 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

In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- Shake well, wet hair, massage onto scalp and rinse.
- For best results, use at least twice a week or as directed by a doctor.

Other Information

Store at Room Temperature

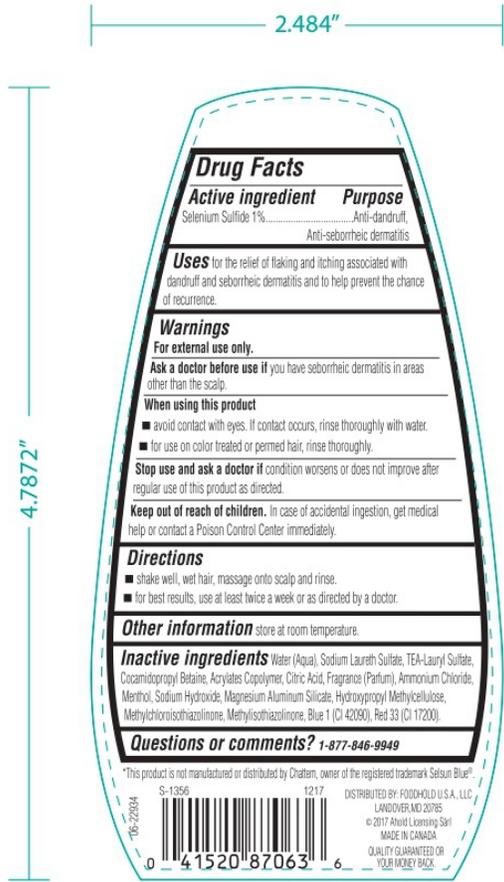
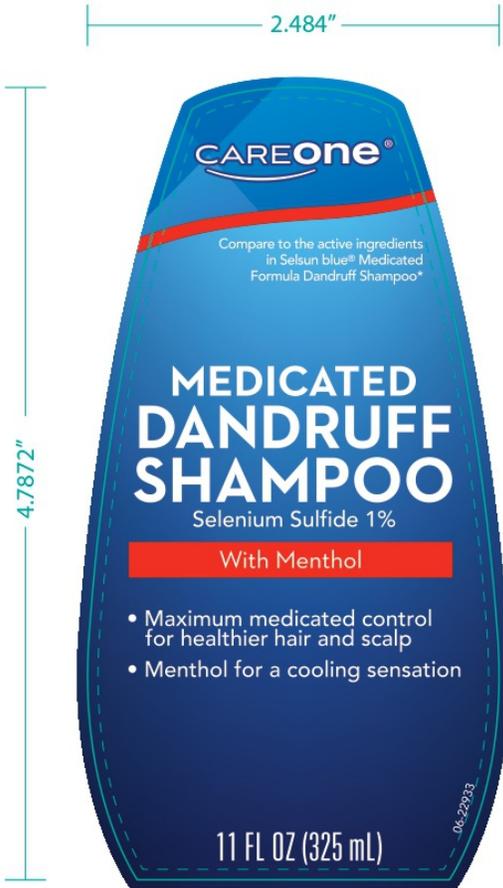
Inactive Ingredients

Water (Aqua), Sodium Laureth Sulfate, TEA-Lauryl Sulfate, Cocamidopropyl Betaine, Acrylates Copolymer, Citric Acid, Fragrance (Parfum), Ammonium Chloride, Menthol, Sodium Hydroxide, Magnesium Aluminium Silicate, Hydroxypropyl Methylcellulose, Methylchloroisothiazolinone, Methylisothiazolinone, Blue 1 (CI 42090), Red 33 (CI 17200).

Questions or comments ?

1-877-846-9949

PDP03



THIS JOB IS PRINTING IN 4-COLOUR PROCESS. PMS TARGETS ARE FOR REFERENCE ONLY.

Northern label group inc. # OF COLOURS: 4 Material: White PP IMPORTANT: PLEASE READ! These colours are designated for reference only. Refer to actual ink samples for exact match. LABEL WILL NOT PROCEED UNTIL ALL ITEMS BELOW HAVE BEEN CHECKED <input type="checkbox"/> Size of Label <input type="checkbox"/> Die Line <input type="checkbox"/> Spelling <input type="checkbox"/> UPC Code <input type="checkbox"/> Copy Layout <input type="checkbox"/> Copy Position <input type="checkbox"/> Colour Break <input type="checkbox"/> Product Code	<input type="checkbox"/> YELLOW 485 Target Col	<input type="checkbox"/> MAGENTA 661 Target Col	<input type="checkbox"/> CYAN 1217 Target Col	<input type="checkbox"/> BLACK	Customer: Apollo DKT#: 7709-C Job Name: 11oz Care One Dandruff Shampoo Description: Medicated with Menthol - 06-22933/06-22934 Date: January 26, 2018 NEW FILE REV# UPC Customer Supplied
	Please indicate any changes that may be needed. An approval of this file is limited to text placement, spelling accuracy and agreement on layout and screen represented colour.				

Client Approved: _____ Changes YES NO _____

selenium sulfide shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (4500 MPA.S) (UNII: T967IEU43C)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
MENTHOL (UNII: L7T10EIP3A)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
WATER (UNII: 059QF0KO0R)	
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	
AMMONIUM CHLORIDE (UNII: 01Q9PC255D)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-025-03	325 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/26/2021	



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Marketing Information

Marketing

Application Number or Monograph

Marketing Start

Marketing End

Category	Citation	Date	Date
OTC monograph final	part358H	08/26/2021	

Labeler - Retail Business Services, LLC (967989935)

Registrant - Apollo Health and Beauty Care (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care		201901209	manufacture(72476-025)

Revised: 11/2022

Retail Business Services, LLC