

**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.*

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**Drug Facts**

**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

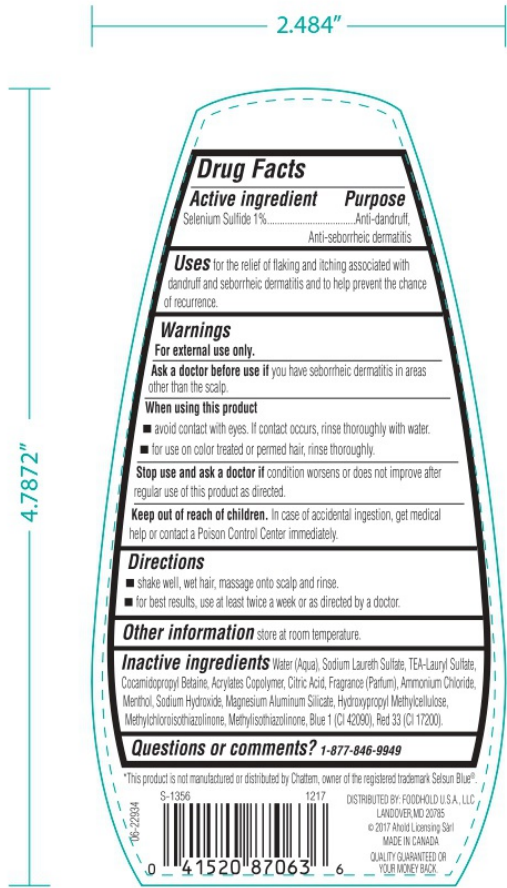
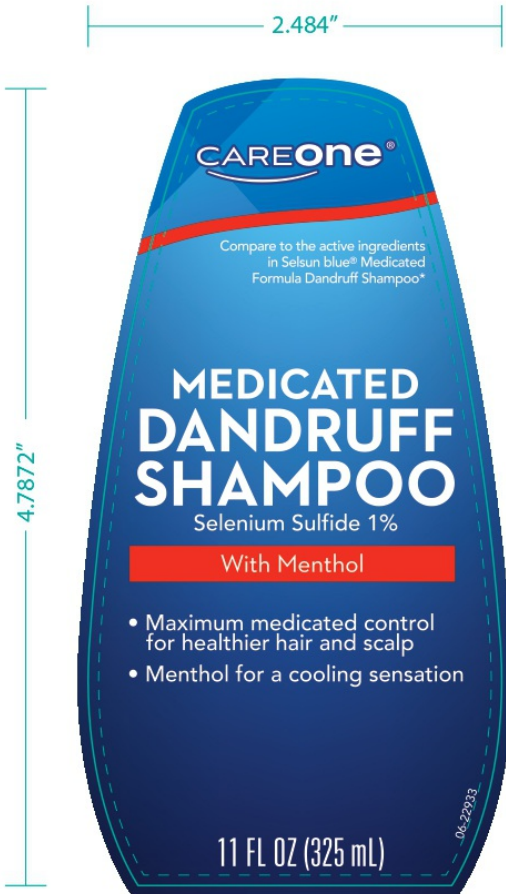
## **Inactive Ingredients**

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.**

<b>Northern</b> label group inc. # OF COLOURS: 4 <b>Material: White PP</b> 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"/> YELLOW 485 Target Col	<input type="checkbox"/> MAGENTA 661 Target Col	<input type="checkbox"/> CYAN	<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.				Changes <input type="checkbox"/> YES <input type="checkbox"/> NO

Client Approved: \_\_\_\_\_ Changes  YES  NO \_\_\_\_\_

selenium sulfide shampoo

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

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



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	<input type="checkbox"/> 485 Target Col <input type="checkbox"/> 661 Target Col	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.

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## Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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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
Spa Dent Inc		203478896	manufacture(72476-025)

Revised: 9/2021

Retail Business Services, LLC