

LEADER MEDICATED DANDRUFF ANTI-SEBORRHEIC DERMATITIS, ANTI-DANDRUFF- selenium sulfide shampoo
Cardinal Health, 110 dba LEADER

Leader™ Medicated Dandruff Shampoo
Anti-Seborrheic Dermatitis, Anti-Dandruff

Drug Facts

Active ingredient

Selenium Sulfide 1%

Purpose

Anti-seborrheic dermatitis, anti-dandruff

Uses

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

Warnings

For external use only

As a doctor before use if

- ◆ condition covers a large area of the body.

When using this product

- ◆ avoid contact with the 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 (1-800-222-1222) right away.

Directions

- ◆ shake well
- ◆ shampoo, then 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 laureth sulfate, ammonium lauryl sulfate, cocamide MEA, cocamidopropyl betaine, magnesium aluminum silicate, hydroxypropyl methylcellulose, fragrance, menthol, chlorphenesin, phenoxyethanol, citric acid, sodium chloride, blue 1, red 33

Questions or comments?

1-866-567-8600

DIST BY CAH, DUBLIN, OH 43017

PRINCIPAL DISPLAY PANEL - 207 mL Bottle Label

LEADER™

NDC 70000-0531-1

Medicated
Dandruff
Shampoo

Selenium Sulfide, 1%
Anti-Seborrheic Dermatitis
Anti-Dandruff

With Menthol

For the Relief
of Seborrheic
Dermatitis
and Dandruff
Symptoms

COMPARE TO
SELSUN BLUE®
active ingredient*

100% Money
Back Guarantee

7 FL OZ (207 mL)

05-3793

LEADER²

NDC 70000-0531-1

Medicated

Dandruff Shampoo

Selenium Sulfide, 1%
Anti-Seborrheic Dermatitis
Anti-Dandruff

With Menthol

For the Relief
of Seborrheic
Dermatitis
and Dandruff
Symptoms

COMPARE TO
SELSUN BLUE[®]
active ingredient*

100% Money
Back Guarantee

7 FL OZ (207 mL)

05-3793

Drug Facts

Active ingredient

Selenium sulfide 1% ... Anti-seborrheic dermatitis, anti-dandruff

Purpose

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

Warnings

For external use only

Ask a doctor before use if

- condition covers a large area of the body.

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 (1-800-222-1222) right away.

Directions

- shake well • shampoo, then 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 laureth sulfate, ammonium lauryl sulfate, cocamide MEA, cocamidopropyl betaine, magnesium aluminum silicate, hydroxypropyl methylcellulose, fragrance, menthol, chlorphenesin, phenoxyethanol, citric acid, sodium chloride, blue 1, red 33

Questions or comments? 1-866-567-8600

*This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Selsun Blue[®].

WARNING: THIS PRODUCT CAN EXPOSE YOU TO CHEMICALS INCLUDING SELENIUM SULFIDE, WHICH IS KNOWN TO THE STATE OF CALIFORNIA TO CAUSE CANCER. FOR MORE INFORMATION GO TO WWW.P65WARNINGS.CA.GOV

DIST BY CAH, DUBLIN, OH 43017 1-800-200-6313
Made in Canada

©2019 CARDINAL HEALTH, LEADER, and LOGOs are trademarks of Cardinal Health. All other marks are the property of their respective owners.

CIN 5573035 REV. 11/19



0 96295 13895 5

05-3794

LEADER MEDICATED DANDRUFF ANTI-SEBORRHEIC DERMATITIS, ANTI-DANDRUFF

selenium sulfide shampoo

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:70000-0531

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
Water (UNII: 059QF0KO0R)	
AMMONIUM LAURETH-5 SULFATE (UNII: 43ZIH89I48)	
Ammonium Lauryl Sulfate (UNII: Q7AO2R1M0B)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
Magnesium Aluminum Silicate (UNII: 6M3P64V0NC)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
Chlorphenesin (UNII: I670DAL4SZ)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
Sodium Chloride (UNII: 451W47IQ8X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics

Color	GREEN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0531-1	207 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/05/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M032	11/05/2019	

Labeler - Cardinal Health, 110 dba LEADER (063997360)

Registrant - Garcoa, Inc. (036464697)

Establishment

Name	Address	ID/FEI	Business Operations
Sigan Industries INC		255106239	MANUFACTURE(70000-0531)

Revised: 3/2024

Cardinal Health, 110 dba LEADER