

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.

Advanced Solution Dandruff Shampoo
Care One 816.000 816AC/AD

Active ingredient

Selenium sulfide 1%

Purpose

Anti-dandruff, Anti-seborrheic dermatitis

Use

helps prevent recurrence of itching, irritation, redness, flaking and scaling associated with dandruff and seborrheic dermatitis

Warnings

For external use only

Ask a doctor before use if

condition covers a large area of the body

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
- for maximum dandruff control, use every time you shampoo

- wet hair, massage onto scalp, rinse, repeat if desired
- for best results use at least twice a week or as directed by a doctor
- if used on bleached, gray, tinted or permed hair, rinse for at least 5 minutes

Inactive ingredients

water, ammonium laureth sulfate, ammonium lauryl sulfate, glycol distearate, cocamide MEA, ammonium xylenesulfonate, sodium citrate, fragrance, amodimethicone, cetyl alcohol, sodium chloride, citric acid, sodium benzoate, stearyl alcohol, disodium EDTA, hydrogen peroxide, hydroxypropyl methylcellulose, methylchlorisothiazolinone, methylisothiazolinone, red 4

adverse reaction

*This product is not manufactured or distributed by Procter & Gamble, distributor of Head & Shoulders Clinical Strength Dandruff Shampoo.

Manufactured by: Vi-Jon, LLC., St. Louis, MO 63114

Questions or Comments? 1-888-593-0593

Made in the USA with US and foreign parts.

principal display panel

CAREONE

Compare to Head & Shoulders

Clinical Strength Dandruff Shampoo

DANDRUFF

SHAMPOO

MAXIMUM STRENGTH

- Regular use helps control dandruff flaking
- No Phthalates
- No Parabens

NET 14.2 FL OZ (420 mL)

CAREone™

Compare to Head & Shoulders®
Clinical Strength Dandruff Shampoo*

DANDRUFF SHAMPOO

MAXIMUM STRENGTH

- Regular use helps control dandruff flaking
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NET 14.2 FL OZ (420 mL)

L0020023FA

DANDRUFF

selenium sulfide shampoo

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:72476-816

Route of Administration	TOPICAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z 69D9E381Q) (SELENIUM SULFIDE - UNII:Z 69D9E381Q)	SELENIUM SULFIDE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURETH-3 SULFATE (UNII: 896SJ235FN)	
AMMONIUM LAURYL SULFATE (UNII: Q7A02R1M0B)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
AMMONIUM XYLENESULFONATE (UNII: 4FZY6L6XCM)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-816-15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	08/18/2021	

Labeler - Retail Business Services, LLC (967989935)

Registrant - Vi-Jon, LLC (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72476-816)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72476-816)

Establishment

Name	Address	ID/FEI	Business Operations
RWM TECHNOLOGIES LLC		626626969	manufacture(72476-816)

Revised: 1/2023

Retail Business Services, LLC