DANDRUFF- selenium sulfide shampoo
AMAZON.COM 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
816.000/816AC

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

DISTRIBUTED BY:

Amazon.com, Services, LLC

Seattle, WA 98109

1-877-485-0385

2021 Amazon.com, Inc. or its affiliates.

All rights reserved.

Amazon.com, Inc or its affiliates.

816.000/816AC

principal display panel

Solimo dandruff shampoo

Selenium sulfide 1%

Maximum strength

14.2 FL OZ (420 mL)

DANDRUFF

selenium sulfide shampoo

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72288-816
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-3 SULFATE (UNII: 896SJ235FN)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
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:72288-816-15	420 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/09/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	12/09/2012	

Labeler - AMAZON.COM SERVICES LLC (128990418)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72288-816)

Establishment

Name	Address	ID/FEI	Business Operations
RWM TECHNOLOGIES LLC		626626969	manufacture(72288-816)