

**DANDRUFF- selenium sulfide shampoo**  
**CVS**

*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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**CVS 816.000/816AC Dandruff Shampoo**

**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

CVS/pharmacy Maximum Strength Dandruff shampoo helps reduce itching, flaking, scaling, irritation and redness

due to severe dandruff and seborrheic dermatitis. This advanced formula cleanses and help relieve itch, leaving hair soft and manageable.

Helps control and protect against dandruff from the first wash

Gentle and pH balanced for everyday use, even for permed or color-treated hair

\*This product is not manufactured or distributed by Procter + Gamble, owner of the registered trademark Head + Shoulders

Distributed by: CVS Pharmacy, Inc.

One CVS Drive, Woonsocket, RI 02895

2013CVS/pharmacy

[www.cvs.com](http://www.cvs.com) 1-800-shop-CVS

Made in the U.S.A. of U.S. and imported parts

### **principal display panel**

CVS pharmacy dandruff shampoo

Maximum strength Selenium sulfide dandruff + seborrheic dermatitis shampoo

Helps relieve stubborn dandruff

Dermatologist tested

Compare to the active ingredient in Head + Shoulders Clinical Strength Dandruff Shampoo\*

14.2 FL OZ (420 mL)



## DANDRUFF

selenium sulfide shampoo

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-589
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Base of

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>AMMONIUM LAURETH-3 SULFATE</b> (UNII: 896SJ235FN)	
<b>AMMONIUM LAURYL SULFATE</b> (UNII: Q7AO2R1M0B)	
<b>GLYCOL DISTEARATE</b> (UNII: 13W7MDN21W)	
<b>COCO MONOETHANOLAMIDE</b> (UNII: C80684146D)	
<b>AMMONIUM XYLENESULFONATE</b> (UNII: 4FZY6L6XCM)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>AMODIMETHICONE (800 CST)</b> (UNII: 363Z2T48P7)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-589-15	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** - CVS (062312574)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(59779-589)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(59779-589)

Revised: 2/2022

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