

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.

Dandruff Shampoo
816

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 1-800-shop-CVS

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

816.000/816AC

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII:Z69D9E381Q)	SELENIUM SULFIDE	10 mg in 1 mL
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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: 2KR89I4HIY)	
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: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 (790752542)

Establishment

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