HEAD AND SHOULDERS CLINICAL STRENGTH DANDRUFF DEFENSE ADVANCED OIL CONTROL- selenium sulfide lotion/shampoo The Procter & Gamble Manufacturing Company

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.

Head and Shoulders ®

Clinical Strength Dandruff Defense Advanced Oil Control Shampoo Drug Facts

Active ingredient

Selenium Sulfide 1%

Purpose

Anti-dandruff, anti-seborrheic dermatitis

Uses

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

Warnings

For external use only.

Ask a doctor before use if you have a condition that covers a large area of the body. avoid contact with 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 of this product as directed Keep this and all drugs out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for best results use <u>at least</u> twice a week or as directed by a doctor.
- for maximum dandruff control, use every time you shampoo.
- shake before use.
- wet hair, massage onto scalp, rinse, repeat if desired.
- caution: if used on bleached, tinted, grey, or permed hair, rinse for 5 minutes.

Inactive ingredients

Water, ammonium laureth sulfate, ammonium lauryl sulfate, glycol distearate, cocamide MEA, ammonium xylenesulfonate, fragrance, sodium citrate, dimethicone, cetyl alcohol, citric acid, sodium chloride, sodium benzoate, disodium EDTA, stearyl alcohol, hydroxypropyl methylcellulose, methylchloroisothiazolinone, methylisothiazolinone, red 4.

Questions (or comments)?

1-800-723-9569

Dist. by PROCTER & GAMBLE, CINCINNATI, OH 45202

PRINCIPAL DISPLAY PANEL - BOTTLE LABEL

head &

shoulders ®

selenium sulfide dandruff & seborrheic dermatitis shampoo Clinical Strength

Dandruff Defense

Advanced Oil Control

Extra Strength Formula

with Refreshing Citrus

13.5 FL OZ (400 mL)



HEAD AND SHOULDERS CLINICAL STRENGTH DANDRUFF DEFENSE ADVANCED OIL CONTROL

selenium sulfide lotion/shampoo

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-525	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z69D9E381Q) (SELENIUM SULFIDE - UNII: Z69D9E381Q)	SELENIUM SULFIDE	1 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
AMMONIUM XYLENESULFONATE (UNII: 4FZY6L6XCM)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:69423- 525-40	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/17/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M032	11/17/2020		

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 5/2023 The Procter & Gamble Manufacturing Company