

**HEAD AND SHOULDERS CLINICAL STRENGTH DANDRUFF DEFENSE INTENSIVE
ITCH RELIEF- 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 Intensive Itch Relief 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 at least 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, sodium lauryl sulfate, glycol distearate, sodium chloride, cocamidopropyl betaine, sodium citrate, sodium xylenesulfonate, dimethicone, menthol, fragrance, citric acid, sodium benzoate, tetrasodium EDTA, hydroxypropyl methylcellulose, mentha piperita (peppermint) oil, mentha arvensis leaf oil, 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

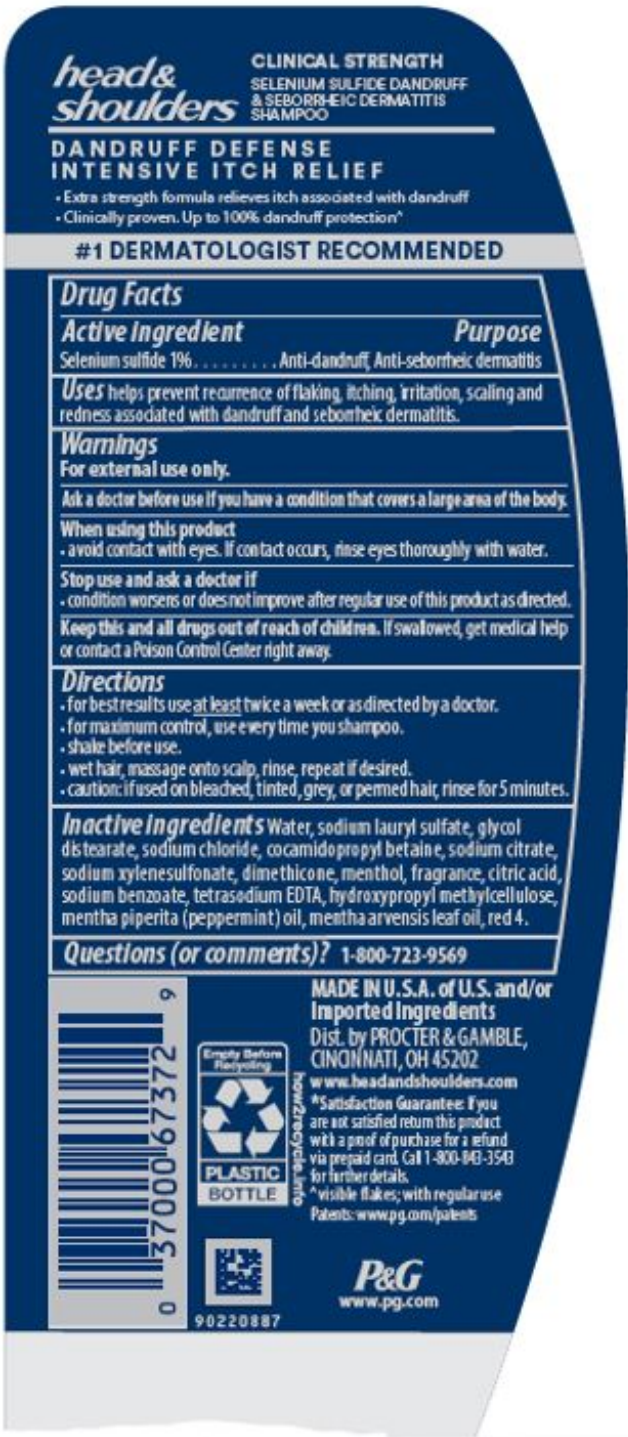
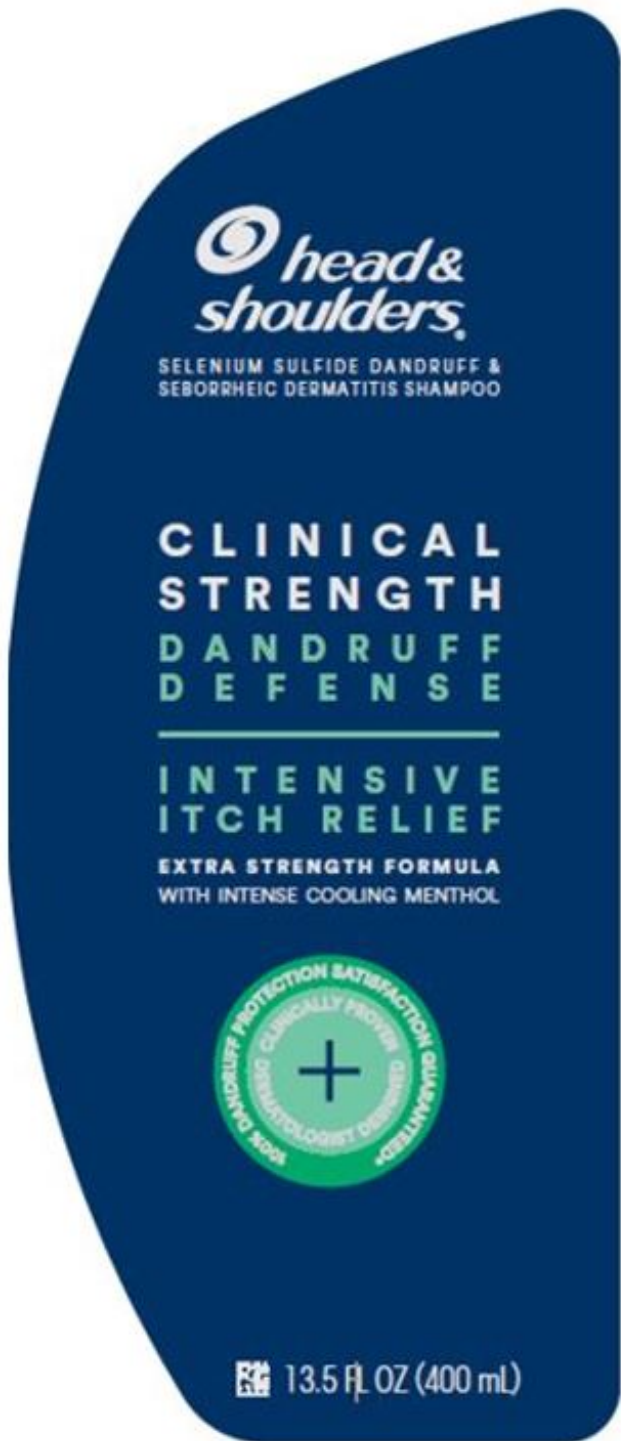
Clinical Strength

Dandruff Defense

Intensive

Itch Relief

13.5 FL OZ (400 mL)



HEAD AND SHOULDERS CLINICAL STRENGTH DANDRUFF DEFENSE INTENSIVE ITCH RELIEF
 selenium sulfide lotion/shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-526
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SELENIUM SULFIDE (UNII: Z 69D9E381Q) (SELENIUM SULFIDE - UNII:Z 69D9E381Q)	SELENIUM SULFIDE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM XYLENESULFONATE (UNII: G4LZF950UR)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
MENTHA ARVENSIS LEAF OIL (UNII: 1AEY1M553N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69423-526-40	400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/17/2020	
2	NDC:69423-526-01	2 in 1 CELLO PACK	01/17/2023	
2		400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

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)