# HEAD AND SHOULDERS CLINICAL STRENGTH DANDRUFF DEFENSE DRY SCALP RESCUE- 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 Dry Scalp Rescue 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, sodium lauryl sulfate, glycol distearate, sodium chloride, cocamidopropyl betaine, sodium citrate, sodium xylenesulfonate, fragrance, dimethicone, citric acid, sodium benzoate, tetrasodium EDTA, hydroxypropyl methylcellulose, honey extract, 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

Dry Scalp

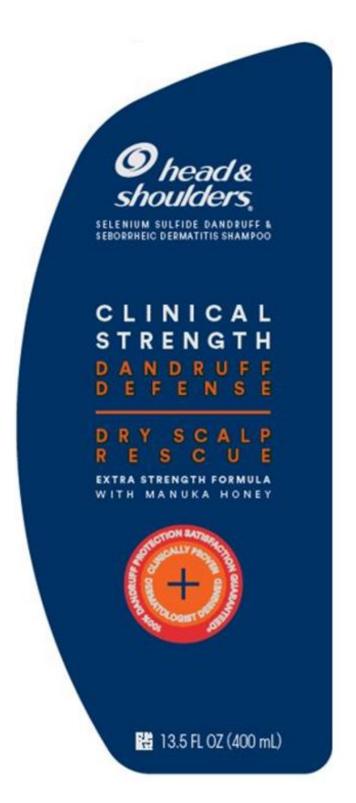
Rescue

Extra Strength Formula

with Manuka Honey

Shampoo

13.5 FL OZ (400 mL)





CLINICAL STRENGTH

### DANDRUFF DEFENSE DRY SCALP RESCUE

Extra strength formula relieves severe dandruff + hydrates dry scalp
 Clinically proven. Up to 100% dandruff protection\*

### #1 DERMATOLOGIST RECOMMENDED

### Drug Facts

Active ingredient

Purpose

Selenium sulfide 116 , Anti-dandruff, Anti-sebonheic 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.

When using this product
- 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 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, fragrance, dimethicone, citric acid, sodium benzoate, tetrasodium EDTA, hydroxypropyl methylcellulose, honey extract, red 4.

### Questions (or comments)? 1-800-723-9569



MADE IN U.S.A. of U.S. and/or



P&G www.pg.com

# **HEAD AND SHOULDERS CLINICAL STRENGTH DANDRUFF DEFENSE** DRY SCALP RESCUE

selenium sulfide lotion/shampoo

| <b>Product Information</b> |                |                    |               |
|----------------------------|----------------|--------------------|---------------|
| Product Type               | HUMAN OTC DRUG | Item Code (Source) | NDC:69423-523 |
| Route of Administration    | TOPICAL        |                    |               |

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

| Inactive Ingredients                         |          |  |
|--|----------|--|
| Ingredient Name                              | Strength |  |
| COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)    |          |  |
| EDETATE DISODIUM (UNII: 7FLD91C86K)          |          |  |
| HONEY (UNII: Y9H1V576FH)                     |          |  |
| 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: 92RU3N3Y10)               |          |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)           |          |  |
| FD&C RED NO. 4 (UNII: X3W0AM1JLX)            |          |  |
| SODIUM CITRATE (UNII: 1Q73Q2JULR)            |          |  |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)   |          |  |

| l | Packaging |                      |  |                         |                       |
|---|-----------|----------------------|--|-------------------------|-----------------------|
|   | #         | Item Code            | Package Description  | Marketing Start<br>Date | Marketing End<br>Date |
|   | 1         | NDC:69423-<br>523-40 | 400 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 11/17/2020              |                       |

| Marketing Information |   |                         |                       |
|-----------------------|---|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph final   | M032  | 11/17/2020              |                       |
|                       |   |                         |                       |

# **Labeler -** The Procter & Gamble Manufacturing Company (004238200)

Revised: 3/2023 The Procter & Gamble Manufacturing Company