HEAD AND SHOULDERS ITCH- selenium sulfide 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 Solutions Itch

Old Spice Swagger

Drug Facts

Active ingredient

Selenium sulfide 1%

Purpose

Anti-dandruff, Anti-seborrheic dermatitis

Uses

for the relief of scalp itch, irritation, redness and flaking 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 OR PRIOR TO USE IN CHILDREN UNDER 2 YEARS.

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. Leave on for several minutes. Rinse. Repeat if desired.

Inactive Ingredients

Water, ammonium laureth sulfate, ammonium lauryl sulfate, glycol distearate, cocamide MEA, ammonium xylenesulfonate,

fragrance, sodium citrate, dimethicone, cetyl alcohol, sodium chloride, citric acid, sodium benzoate, stearyl alcohol, disodium EDTA, hydroxypropyl methylcellulose, methylchloroisothiazolinone, methylisothiazolinone.

Questions (or comments)?

1-800-723-9569

Dist. by PROCTER & GAMBLE, CINCINNATI, OH 45202

PRINCIPAL DISPLAY PANEL - 130 mL Bottle Label

NEW

 $\begin{array}{c} \text{head \&} \\ \text{shoulders }_{\,\mathbb{R}} \end{array}$

CLINICAL

SOLUTIONS

SELENIUM SULFIDE

DANDRUFF & SEBORRHEIC DERMATITIS SHAMPOO

ITCH SHAMPOO

Up To 7-Day Protection

Itch + Dryness Redness +

CLINICALLY PROVEN

130 mL (4.3 FL OZ



· Protection starts from the first wash

- Leaves hair smelling fresh and feeling clean
- Gently moisturizes to leave hair soft and manageable
- From the #1 US Dermatologist Recommended Brand
- Try Clinical Solutions Leave-On Dandruff Treatment for 24hr dandruff and itch protection

After 200+ clinical trials, Head & Shoulders, maker of the World's #1 dandruff shampoo presents Clinical Solutions, the only specialist collection of its kind. Its clinically proven active ingredients give you your healthlest scalp by immediately targeting and keeping away serious scalp issues up to all week long.

Discover more at www.headandshoulders.com

symptoms associated with dandruff and seborrheic dermatitis

- · Protection efficace dès la première
- · Laisse un parfum frais et une sensation de propreté
- Hydrate en douceur pour des cheveux doux au toucher et faciles à colffer
- De la marque la plus recommandée par les dermatologues aux États-Unis
- Essayez le traitement antipelliculaire sans rinçage Clinical Solutions pour une protection contre les pellicules et les démangealsons qui dure 24 h

Après plus de 200 essais cliniques, Head & Shoulders, le fabricant du shampooing antipelliculaire le plus populaire au monde, présente ses produits Clinical Solutions, la seule collection spécialisée en son genre. Ses ingrédients actifs sont éprouvés en clinique pour procurer un cuir chevelu plus sain en ciblant Instantanément les problèmes graves et vous en protège pendant toute la semaine.

Apprenez-en plus au www.headandshoulders.com

* symptômes associés aux pellicules et à la dermatite séborrhéique



Drug Facts/Renseignements sur le produit Active ingredient/Ingrédient actif : Purpose/Fonction

Use Attilisation:

for the relief of scalp fich, intiation, redness and finding associated with dandraff and sationneis dermatilis. I pour le scatagement des démangacions, de l'imfation, des rougeurs et de la desquanazion du cuir chereiu associées aux pellicules et à la demazita sébont-léque.

Warnings:/Mise en garde ; or edenal ese only.Réservé à l'u nearmings mose or year or year.
Ank a doctor before use If you have a condition that cowin a large area of the help. Consoller un médedin acond that best on du produit al you a condition that cowin a large area of the help. Consoller un médedin acond that best on du produit al you acondition mocument une gande partie de corps. When using this product = and confact with eyes. If confact occurs, rince thoroughly with water, Em utilities in co-product, éviter le confact avec les yeur. En cas de confact, les rincer à final avec de l'ess.

Step use and each of a check in 1- condition we need to be set in prove offer regular one of this product on directed OR PRIOR TO USE IN CHILDREN UNICES 275-585. Commer Français de consultar on makedan et, quite individuale estadaire de consultar on makedan condeire partiale estadaire de consultar on makedan condeire partiale estadaire de consultar partiale estadaire de consultar partiale estadaire de consultar partiale estadaire de consultar partiale estadaire partiale estadaire partiale estadaire partiale estadaire partiale estadaire partiale estadaire estad

- lirections:/Mode d'emploi: fur led results use <u>al leug</u>t balce a week or as directed by a doctor Julius d'obtenir de meliteurs résultats, differe <u>sa moins</u> deux tois par exemite un lei qu'indiqué par un rédiscir.
- for maximum control, use every time you shampou, pour un contrôle maximal, efficer à charpe et an myor big, shake before use Agiter avant l'emple).
- wel fait, massage outs scalp, Leuve on for several minutes. Nase, Repect II desired,/modifier les cheveux, masser sur le cuir clevels. Luisser agir plusieurs minutes. Rincer. Ripatier au besoin.

Inactive ingredients:/Ingrédients inactifs : Witer eur en noten hureth suffie, un noten kurjt suffie dycol dislearate, cocamide NEA, ammonium xytenesulfonate, hugrance/parium, sodium clirate, dimethicone, celyl alcohol, sodum chloride, citric acid, sodum berzoate, ate sryf skotkal, disodium EDTA, hydrocypropyl methylcellulose, methylchlorokothiazolinone, methylsothiaz olinone.

Questions (or comments/ou commentaires)? 1-900-772-1999

N ACE I I U.S.A. of U.S. and/or imported ingredients/FAIT AUX E.-U. avec de singuédie ats américains et/outing artés Dist. by/par PROCTER AGAMBLE, CONCOMMAT, OH 45202 angle: NOROMFO, OM MSW 105 www.headandshoulders.com Palests/Brevels : www.pg.com/palests



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HEAD AND SHOULDERS ITCH

selenium sulfide shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69423-154
Route of Administration	TOPICAL		

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

STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
WATER (UNII: 059QF0KO0R)		
AMMO NIUM LAURETH-3 SULFATE (UNII: 896SJ235FN)		
AMMO NIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
GLYCOL DISTEARATE (UNII: 13W7MDN21W)		
AMMO NIUM XYLENESULFO NATE (UNII: 4FZY6L6 XCM)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
COCO MONOETHANOLAMIDE (UNII: C80684146D)		
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69423-154- 13	130 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/17/2016	05/24/2021
2	NDC:69423-154- 25	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/17/2016	05/24/2021

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part358H	11/17/2016	05/24/2021	

Labeler - The Procter & Gamble Manufacturing Company (004238200)

Revised: 6/2019 The Procter & Gamble Manufacturing Company