TOPCARE THERAPEUTIC ANTI-DANDRUFF ANTI-DANDRUFF, ANTI-SEBORRHEIC DERMATITIS, ANTI-PSORIASIS- coal tar shampoo Topco Associates, LLC

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.

TopCare™ Therapeutic Anti-Dandruff Shampoo Anti-dandruff, anti-seborrheic dermatitis, anti-psoriasis

Drug Facts

Active ingredient

Solubilized coal tar extract 2.0% (Coal Tar, 0.5%)

Purpose

Anti-dandruff, anti-seborrheic dematitis, anti-psoriasis

Use

controls the symptom of:

dand	Iruff

seborrheic dermatitis

psoriasis

Warnings

For external use only

Ask a doctor before use if condition covers a large part of the body.

When using this product

$\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ $	roughly with water.
--	---------------------

- use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application.
- $\hfill \square$ do not use for prolonged periods without consulting a doctor
- do not use this product with other forms of psoriasis therapy such as ultra violet radiation or prescription drugs unless directed to do so by a doctor.

Stop use and ask a doctor if condition worsens or does not improve after regular use of this product as directed.

Keep 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
wet hair thoroughly
massage shampoo into the scalp
lather. Leave on hair and scalp for several minutes
rinse and repeat

Other information

store away from direct sunlight
in rare instances, discoloration of gray, blonde, bleached or tinted hair may occur

Inactive ingredients

water, sodium laureth sulfate, cocamide MEA, cocamidopropyl betaine, laureth-4, fragrance, polysorbate 20, citric acid, sodium chloride, disodium EDTA, phenoxyethanol, methylchloroisothiazolinone, methylisothiazolinone, red 40, blue 1, yellow 5, yellow 6.

Questions or comments?

1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 251 mL Bottle Label

TopCare™ beauty

THERAPEUTIC ANTI-DANDRUFF SHAMPOO

with 2% Coal Tar Topical Solution (0.5% Coal Tar)

Compare to NEUTROGENA® T/Gel Shampoo*

ORIGINAL STRENGTH

Fights itching & flaking

Controls the symptoms of dandruff, psoriasis & seborrheic dermatitis

PARABEN & PHTHALATE FREE 8.5 FL OZ (251 mL) 05-4365



THERAPEUTIC

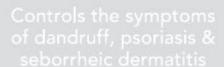
ANTI-DANDRUFF SHAMPOO

with 2% Coal Tar Topical Solution (0.5% Coal Tar)

Compare to NEUTROGENA® T/Gel Shampoo*

ORIGINAL STRENGTH

Fights itching & flaking



PARABEN &

8.5 FL OZ (251 mL)

05-4365

Drug Facts

Active ingredient

Purpose

Solubilized coal tar extract 2.0%

(coal tar, 0.5%) Anti-dandruff, anti-seborrheic dermatitis, anti-psoriasis

Use controls the symptoms of: • dandruff • seborrheic dermatitis • psoriasis

Warnings

For external use only

Ask a doctor before using this product if condition covers a large area of the body.

When using this product

avoid contact with the eyes. If contact occurs, rinse eyes thoroughly with water
 use caution in exposing skin to sunlight after applying this product. It may increase your tendency to sunburn for up to 24 hours after application.
 do not use for prolonged periods without consulting a doctor.
 do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a doctor.

Stop use and ask a doctor if condition worsens or does not improve after regular use of this product as directed.

Keep 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 • wet hair thoroughly • massage shampoo into the scalp • lather, leave on hair and scalp for several minutes. • rinse and repeat

Other information • store away from direct sunlight • in rare instances, discoloration of gray, blonde, bleached or tinted hair may occur

Inactive ingredients water, sodium laureth sulfate, cocamide MEA, cocamidopropyl betaine, laureth-4, fragrance, polysorbate 20, citric acid, sodium chloride, disodium EDTA, phenoxyethanol, methylchloroisothiazolinone, methylisothiazolinone, red 40, blue 1, yellow 5, yellow 6.

C Questions or comments? 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO GLBA1121 QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com
MADE IN CANADA



Scan here for more information or call 1-888-423-0139

✓ QUALITY GUARANTEED

*This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., owner of the registered trademarks Neutrogena® T/Gel®.



2

05-4366

TOPCARE THERAPEUTIC ANTI-DANDRUFF ANTI-DANDRUFF, ANTI-SEBORRHEIC DERMATITIS, ANTI-PSORIASIS

coal tar shampoo

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76162-190	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Coal Tar (UNII: R533ESO2EC) (Coal Tar - UNII:R533ESO2EC)	Coal Tar	5 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Sodium Laureth-3 Sulfate (UNII: BPV390UAP0)			
Coco Monoethanolamide (UNII: C80684146D)			
Cocamidopropyl Betaine (UNII: 50CF3011KX)			
Laureth-4 (UNII: 6HQ855798J)			
Polysorbate 20 (UNII: 7T1F30V5YH)			
Citric Acid Monohydrate (UNII: 2968PHW8QP)			
Sodium Chloride (UNII: 451W47IQ8X)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
Phenoxyethanol (UNII: HIE492ZZ3T)			
Methylchloroisothiazolinone (UNII: DEL7T5QRPN)			
Methylisothiazolinone (UNII: 229D0E1QFA)			
FD&C Red No. 40 (UNII: WZB9127XOA)			
FD&C Blue No. 1 (UNII: H3R47K3TBD)			
FD&C Yellow No. 5 (UNII: I753WB2F1M)			
FD&C Yellow No. 6 (UNII: H77VEI93A8)			

Product Characteristics				
Color	BROWN	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

ı u	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		251 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/31/2022		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part358H	08/31/2022		

Labeler - Topco Associates, LLC (006935977)

Registrant - Garcoa, Inc. (036464697)

Establishment					
Name	Address	ID/FEI	Business Operations		
Sigan Industries INC.		255106239	MANUFACTURE(76162-190)		

Revised: 9/2022 Topco Associates, LLC