THERAPEUTIC- 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.

Coal Tar Shampoo 205.004/205AH

Active ingredient

2.5% Coal Tar Topical Solution USP (0.5% Coal Tar)

Purpose

Anti-Dandruff

Use

Controls the symptoms of:

- dandruff
- seborrheic dermatitis
- psoriasis

Warnings

For external use only

When using this product

- do not get into eyes. If contact occurs, rinse eyes thoroughly wih water.
- use caution in exposing skin to sunlight after applying this product. It may increase sunburn for up to 24 hours after application
- do not use for prolonged periods without consulting a doctor
- do not use 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

- wet hair thoroughly
- massage shampoo into the scalp
- lather. Leave on hair and scalp for several minutes
- rinse and repeat
- for best results use at least twice a week or as directed by a doctor

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, laureth-4, fragrance, sodium chloride, cocamidopropyl betaine, methylchloroisothiazolinone, methylisothiazolinone, citric acid, tetrasodium EDTA, caramel, red 4

disclaimer

This product is not manufactured or distributed by the Neutrogena Corporation, distributor of Neutrogena T/Gel Shampoo

Adverse Reactions

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007-1015

1-888-423-0139

topcare@topco.com

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principal display panel

TopCare beauty

THERAPEUTIC

ANTI-DANDRUFF SHAMPOO

with 2.5% Coal Tar Topical Solution

USP (0.5% Coal tar)

Compare to

NEUTROGENA

T/Gel Shampoo

ORIGINAL STRENGTH

Fights itchy, flaky scalp

Controls the symptoms of dandruff, psoriasis & seborrheic dermatitis

8.5 FL OZ (251 mL)



THERAPEUTIC

coal tar shampoo

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-205

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
mgreatent name	busis of strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	25 mg in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)		
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)		
LAURETH-4 (UNII: 6HQ855798J)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
EDETATE SODIUM (UNII: MP1J8420LU)		
CARAMEL (UNII: T9D99G2B1R)		
FD&C RED NO. 4 (UNII: X3W0AM1JLX)		

l	Packaging				
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
	1		251 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/27/2005	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	12/27/2005	

Labeler - Topco Associates LLC (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-205)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-205)

Revised: 2/2023 Topco Associates LLC