# THERAPEUTIC- coal tar shampoo DZA Brands, 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.

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# Coal Tar Shampoo 205.004/205AH

#### **Claims**

**Healthy Accents** 

Therapeutic

Shampoo

coal tar

anti-dandruff shampoo

#### **Active ingredients**

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

# Ask a doctor before use if you have

a condition which covers a large part of the body

# When using this product

- do not get into 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 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 throoughly
- 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 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 Neutorgena Corporation, distributor of Neutrogena T/G Shampoo

#### **Adverse Reactions**

Distributed by: DZA Brands, LLC

Salisbury, NC 28147

Scarborough, ME 0474

For product questions or concerns contact us at 1-866-322-2439. Please include UPC number and code from package.

# principal display panel

healthy

accents

therapeutic

shampoo

coal tar

anti-dandruff shampoo

2.5% coal tar topical solution usp

(0.5% coal tar)

compare to the active

ingredient in Neutrogena

Therapeutic T/Gel Shampoo

8.5 FL OZ (251 mL)



# therapeutic shampoo

coal tar anti-dandruff shampoo 2.5% coal tar topical solution usp (0.5% coal tar)

controls the symptoms of: psoriasis, seborrheic dermatitis & dandruff

compare to the active ingredient in Neutrogena Therapeutic T/Gel Shampoo\*



8.5 FL OZ (251 mL)

### **THERAPEUTIC**

coal tar shampoo

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:55316-205

**Route of Administration** TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	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 SULFATE (UNII: BPV390UAP0)		
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
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: X3W0AM1ILX)		

F	Packaging			
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316- 205-23	1 in 1 CARTON	05/08/2008	
1		251 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	part358H	05/08/2008	

# Labeler - DZA Brands, LLC (090322194)

# Registrant - Vi-Jon, LLC (790752542)

# **Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55316-205)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55316-205)

Revised: 2/2023 DZA Brands, LLC