THERAPEUTIC ANTI-DANDRUFF- coal tar shampoo Winco Foods, 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.

Drug Facts 205.003/205AG-AH

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

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 prescriptin 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 leat 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

Questions?

Call 800-824-1706

Monday - Friday 9am - 4pm MST

Dis claimer

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

principal display panel

NDC 11673-205-23

t plus

therapeutic

dandruff

shampoo

Coompare to Neutrogena

T/Gel Shampoo

2.5% coal tar topical solution USP (0.5% coal tar)

fights itchy, flakey scalp

helps control the symptoms of

dandruff

psoriasis

seborrheic dermatitis

up & up

8.5 FL OZ (251.3 mL)

t plus therapeutic dandruff shampoo

Compare to Neutrogena® T/Gel® Shampoo*

2.5% coal tar topical solution USP (0.5% coal tar)

fights itchy, flaky scalp

helps control the symptoms of dandruff psoriasis

seborrheic dermatitis



2001535

8.5 FL OZ (251.3 mL)

THERAPEUTIC ANTI-DANDRUFF

coal tar shampoo

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Product	Information

HUMAN OTC DRUG NDC:67091-160 Product Type Item Code (Source)

TOPICAL **Route of Administration**

Active Ingredient/Active Moiety

Ingredient Name	Basis 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)		
SO DIUM LAURETH SULFATE (UNII: BPV390 UAP0)		
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0 VTB1)		
LAURETH-4 (UNII: 6HQ855798J)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)		
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)		
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)		
CITRIC ACID MONOHYDRATE (UNII: 2968 PHW8 QP)		
EDETATE SO DIUM (UNII: MP1J8420 LU)		
CARAMEL (UNII: T9D99G2B1R)		

Packaging

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	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:67091-160- 16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/17/20 14	

Marketing Information

FD&C RED NO. 4 (UNII: X3W0 AM1JLX)

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	11/17/20 14	

Labeler - Winco Foods, LLC (056098817)

$\boldsymbol{Registrant - \text{Vi-Jon} (790752542)}$

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(67091-160)

Revised: 4/2020 Winco Foods, LLC