

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.

Drug Facts

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 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 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 MIPA, laureth-4, fragrance, cocamidopropyl betaine, citric acid, sodium chloride, tetrasodium EDTA, methylparaben, propylparaben, imidazolidinyl urea, caramel, red 4

Disclaimer

This product is not manufactured or distributed by the Neutrogena 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)

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)

healthy
accents®

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	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 SULFATE (UNII: BPV390UAP0)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
LAURETH-4 (UNII: 6HQ855798J)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
IMIDUREA (UNII: M629807ATL)	
EDETATE SODIUM (UNII: MP1J8420LU)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CARAMEL (UNII: T9D99G2B1R)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-205-23	1 in 1 CARTON		
1		251 mL in 1 BOTTLE, PLASTIC		

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 (790752542)**Establishment**

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

