

THERAPEUTIC- coal tar shampoo

Vi-Jon, Inc.

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 Dandruff Shampoo

850

Active ingredient

5% Coal tar topical solution USP (1% Coal tar)

Purpose

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 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.

California Proposition 65 Warning

This product contains chemicals known in the State of California to cause cancer.

Directions

- for best results use at least twice a week or as directed by a doctor
- wet hair thoroughly
- massage shampoo into 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 MIPA, cocamidopropyl betaine, polysorbate 20, laureth-4, bishydroxyethyl dihydroxypropyl stearammonium chloride, PEG-120 methyl glucose dioleate, tetrasodium EDTA, citric acid, fragrance, imidazolidinyl urea, methylparaben, propylparaben, caramel, red-4

*This product is not manufactured or distributed by the Neutrogena T/Gel Therapeutic Shampoo Extra Strength.

Manufactured by: Vi-Jon, Inc., St. Louis, MO 63114

Questions or Comments? 1-888-593-0593

850.002/850AC-497AF

Principal display panel

Mountain falls

Compare to Neutrogena*

Fights itchy, flaky scalp

Leaves hair shiny and manageable

Gentle fragrance

Controls the symptoms of:

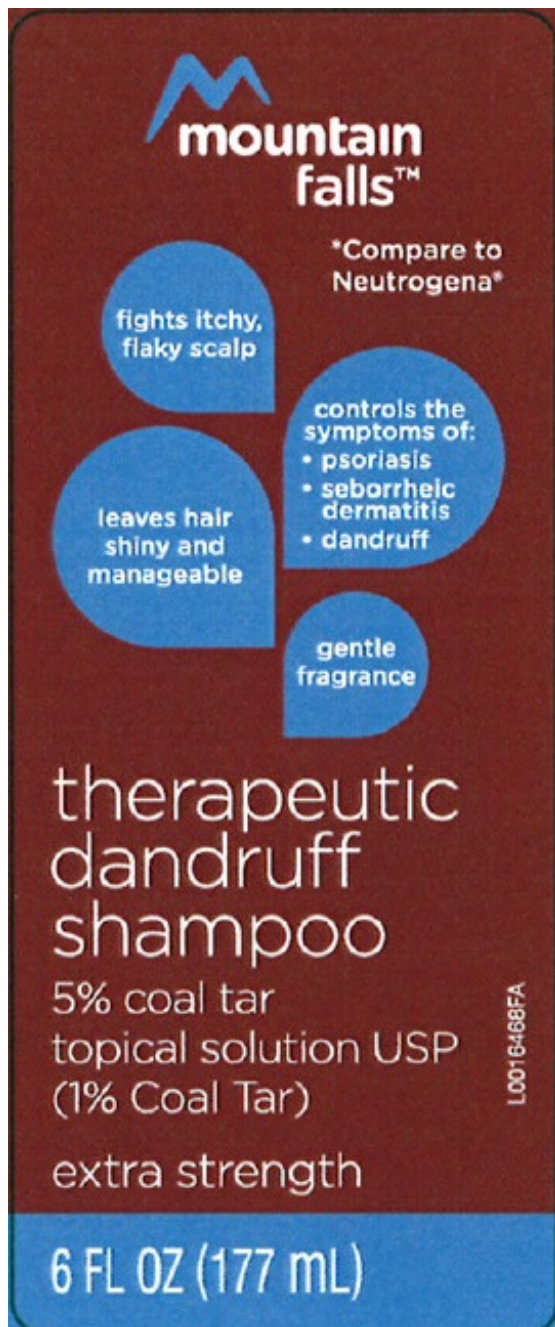
- psoriasis
- seborrheic dermatitis
- dandruff

Therapeutic dandruff shampoo

5% coal tar topical solution USP (1% coal tar)

Extra strength

6 FL OZ (177 mL)



THERAPEUTIC

coal tar shampoo

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0850
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)	COAL TAR	1.02 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
LAURETH-4 (UNII: 6HQ855798J)	
BISHYDROXYETHYL DIHYDROXYPROPYL STEARAMMONIUM CHLORIDE (UNII: 32II08O72A)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
IMIDUREA (UNII: M629807ATL)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (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:0869-0850-30	1 in 1 CARTON	12/01/2017	
1		177 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	12/01/2017	

Labeler - Vi-Jon, Inc. (790752542)**Registrant** - Vi-Jon, Inc. (790752542)**Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc.		790752542	manufacture(0869-0850)