#### THERAPEUTIC- coal tar shampoo CVS Pharmacy, 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.

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Coal Tar Dandruff Shampoo 850

#### Active ingredient

5% Coal Tar Topical Solution USP (1% Coal Tar)

#### Purpose

Anti-dandruff

#### Use

controls the symoptoms 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 occurrs, 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 reqular 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 know 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
- masage 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, cocamidipropl betaine, polysorbate 20, laureth-4, bishydroxyethly 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 Johnson & Johnson Corporation, owner of the registered trademark Neutrogena T/Gel.

Distributed by: CVS Pharmacy, Inc.

One CVS/pharmacy

CVS.com 1-800-SHOP-CVS

Made in the U.S.A. with U.S. and foreign compents.

850.002/850AC-497AF

#### **Principal Display Panel**

CVS Health

Compare to Neutrogena T/Gel Therapeutic Shampoo\*

EXTRA STRENGTH

Therapeutic Dandruff Shampoo

5% COAL TAR TOPICAL SOLUTION USP (1% COAL TAR)

Controls redness, intense itching & flaking of severe scalp conditions

Controls the symptoms of dandruff, sevorrheic dermatitis & psoriasis

6 FL OZ (177 mL)



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#### THERAPEUTIC

coal tar shampoo

| Product TypeHUMAN OTC DRUGItem Code (Source)NDC:59779-850 | Product Information     |                |                    |               |  |  |
|---|-------------------------|----------------|--------------------|---------------|--|--|
|   | Product T ype           | HUMAN OTC DRUG | Item Code (Source) | NDC:59779-850 |  |  |
| Route of Administration TOPICAL                           | Route of Administration | TOPICAL        |                    |               |  |  |

| Active Ingredient/Active Moiety  |  |              |                       |  |  |  |  |
|--|--|--------------|-----------------------|--|--|--|--|
| Ingredient Name Basis of Strength S  |  |              |                       |  |  |  |  |
| COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)COAL TAR1.02 mg in 1 m |  |              |                       |  |  |  |  |
|  |  |              |                       |  |  |  |  |
| Inactive Ingred  | ients  |              |                       |  |  |  |  |
| Ingredient Name Str  |  |              |                       |  |  |  |  |
| water (UNII: 059QF0KO0R)   |  |              |                       |  |  |  |  |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0)                                      |  |              |                       |  |  |  |  |
| COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)                                   |  |              |                       |  |  |  |  |
| COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)                                      |  |              |                       |  |  |  |  |
| POLYSORBATE 20 (UNII: 7T1F30V5YH)  |  |              |                       |  |  |  |  |
| LAURETH-4 (UNII: 6HQ855798J)   |  |              |                       |  |  |  |  |
| BISHYDRO XYETHYL DIHYDRO XYPRO PYL STEARAMMO NIUM CHLO RIDE (UNII: 321108072A) |  |              |                       |  |  |  |  |
| PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)                             |  |              |                       |  |  |  |  |
| EDETATE SO DIUM (UNII: MP1J8420LU)   |  |              |                       |  |  |  |  |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)                                     |  |              |                       |  |  |  |  |
| IMIDUREA (UNII: M6   |  |              |                       |  |  |  |  |
| METHYLPARABEN (UNII: A218 C7HI9T)  |  |              |                       |  |  |  |  |
| PROPYLPARABEN (UNII: Z8IX2SC10H)   |  |              |                       |  |  |  |  |
| CARAMEL (UNII: T9  | D99G2B1R)  |              |                       |  |  |  |  |
| FD&C RED NO. 4 (UNII: X3W0 AM1JLX)   |  |              |                       |  |  |  |  |
|  |  |              |                       |  |  |  |  |
|  |  |              |                       |  |  |  |  |
| Packaging  |  |              |                       |  |  |  |  |
| # Item Code  | Package Description  |              | Marketing End<br>Date |  |  |  |  |
| 1 NDC:59779-850-<br>30   | 1 in 1 CARTON  | 0 3/15/20 16 |                       |  |  |  |  |
| 1  | 177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product |              |                       |  |  |  |  |

### **Marketing Information**

| Marketing Category Ap     | pplication Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|----------------------|--------------------|
| OTC monograph final part3 | 358 H                                   | 0 3/15/20 16         |                    |

# Labeler - CVS Pharmacy, Inc. (062312574)

## Registrant - Vi-Jon (790752542)

| Establishm | ent     |           |                            |
|------------|---------|-----------|----------------------------|
| Name       | Address | ID/FEI    | <b>Business Operations</b> |
| Vi-Jon     |         | 790752542 | manufacture(59779-850)     |

Revised: 5/2020