

SKIN AND SCALP- coal tar shampoo

Albra Dewyn 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.

Skin & Scalp Shampoo / Body Wash

DRUG FACTS

Active ingredients Purpose

Coal tar solution 8.5% v/vPsoriasis, Atopic & Seborrheic
(Equivalent to 1.7% Coal tar)..... Dermatitis & Dandruff

USES

Controls symptoms of Psoriasis, Atopic & Seborrheic Dermatitis & Dandruff. • Relieves itching, flaking, scaling, & scalp irritation.

WARNINGS

For external use only: Ask a doctor before use if your body has a condition that which covers a large part of the body. Keep out of reach of children. When using this product: Do not use for a prolonged period of time without consulting a doctor. Do not use with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed by a doctor. Avoid contact with 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. Stop use and ask a doctor if condition worsens or does not improve after regular use of this product as directed. If swallowed, get medical help or contact a Poison Control Center right away.

DIRECTIONS

Shake well, for best results use at least twice a week or directed by a doctor. For shampooing, wet hair thoroughly, massage shampoo into the scalp. Lather, leave on scalp for several minutes. Rinse and repeat. For body wash, add a small amount to damp wash cloth and wash the affected areas. Rinse and repeat

Controls symptoms of: • Seborrheic Dermatitis, • Psoriasis, • Minor & Severe Dandruff, • Relief of scalp & skin itching, irritation & flaking associated with Atopic Dermatitis

OTHER INFORMATION

In rare instances, discoloration of gray, blonde, bleached or tinted hair may occur.

INactive

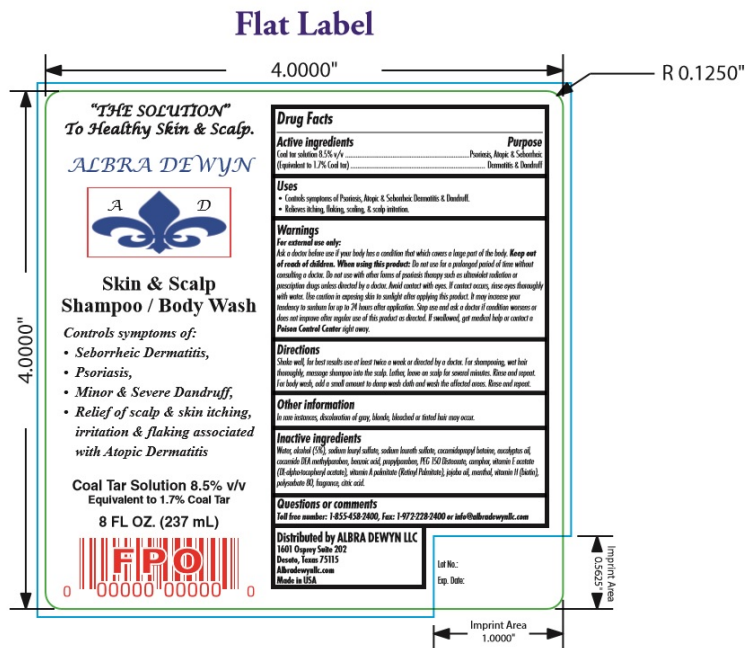
Inactive ingredients Water, alcohol (5%), sodium lauryl sulfate, sodium laureth sulfate, cocamidopropyl betaine, eucalyptus oil, cocamide DEA methylparaben, benzoic acid, propylparaben, PEG 150 Distearate, camphor, vitamin E acetate (DL-alpha-tocopheryl acetate), vitamin A palmitate (Retinyl Palmitate), jojoba oil, menthol, vitamin H (biotin), polysorbate 80,

fragrance, citric acid.

questions or comments

Questions or comments Toll free number: 1-855-458-2400, Fax: 1-972-228-2400 or info@albradewynllc.com

Uses • Controls symptoms of Psoriasis, Atopic & Seborrheic Dermatitis & Dandruff. • Relieves itching, flaking, scaling, & scalp irritation.



SKIN AND SCALP

coal tar shampoo

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59 151-645
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)		COAL TAR	17 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
EUCALYPTUS OIL (UNII: 2R04ONI662)			
COCAMIDOPROPYL DIMETHYLAMINE PROPIONATE (UNII: 83750MLC4A)			
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)			
CAMPHOR (NATURAL) (UNII: N20HL7Q941)			
JOJOBA OIL (UNII: 724GKU717M)			
BIOTIN (UNII: 6SO6U10H04)			

POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
BENZOIC ACID (UNII: 8SKN0B0MM)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
MENTHOL (UNII: L7T10EIP3A)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59151-645-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	09/01/2016	

Labeler - Albra Dewyn LLC (069451336)

Establishment

Name	Address	ID/FEI	Business Operations
Albra Dewyn LLC		069451336	manufacture(59151-645)

Revised: 9/2016

Albra Dewyn LLC