

SKIN AND SCALP BODY- coal tar lotion

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 Lotion

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 result use twice daily or directed by doctor.

Other Information

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

Inactive Ingredients

Purified water, glycerin (from coconut oil), stearic acid (from coconut oil), pure plant oil complex (soy & jojoba oils), cetyl palmitate (from palm oil), eucalyptus oil, cetyl alcohol (from palm oil), poly sorbate (from palm oil), glyceryl stearate (from vegetable sources), cetyl alcohol (from palm oil), aminodimethicone (from silica), phenoxyethanol and ethylhexylglycerin (preservative complex from plant source), camphor, menthol, methylparaben, benzoic acid, propylparaben, PEG 150 distearate, vitamin E acetate (DL-alpha-tocopheryl acetate), vitamin A palmitate (Retinyl Palmitate), vitamin H (biotin), polysorbate 80, citric acid.

Question or Comments

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

Uses

controls symptoms of:

- Seborrheic Dermatitis

- Psoriasis
- Minor & severe dandruff
- relief of sclap & skin itching, irritation & flaking associated with Atopic Dermatiti

Drug Fact

Active Ingredients Purpose

Coal tar solution 1.7% v/v.....Psoriasis, Atopic & seborrheic
 (equivalent to 0.5% coal tar).....Dermatitis & Dandruff

label



SKIN AND SCALP BODY			
coal tar lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59 151-646
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC)		COAL TAR	0.5 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)				
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)				
BIOTIN (UNII: 6SO6U10H04)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
WATER (UNII: 059QF0KO0R)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
MENTHOL (UNII: L7T10EIP3A)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
BENZOIC ACID (UNII: 8SKN0B0MIM)				
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)				
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)				
GLYCERIN (UNII: PDC6A3C0OX)				
SOYBEAN OIL (UNII: 241ATL177A)				
CETYL PALMITATE (UNII: 5ZA2S6B08X)				
EUCALYPTUS OIL (UNII: 2R04ONI662)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
AMODIMETHICONE (800 CST) (UNII: 363Z2T48P7)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
JOJOBA OIL (UNII: 724GKU717M)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59151-646-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/03/2016	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part358H	10/03/2016	

Labeler - Albra Dewyn LLC (069451336)

Establishment

Name	Address	ID/FEI	Business Operations
Albra Dewyn LLC		069451336	manufacture(59151-646)

