

PSORIASIN PROBLEM SKIN FORMULA- coal tar cream

Alva-Amco Pharmcal Companies, 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.

Active ingredient

Coal tar 0.5% (from Coal Tar Topical Solution, USP 20%)

Purpose

Psoriasis / Seborrheic Dermatitis Treatment

Uses

For the relief of symptoms associated with psoriasis and/or seborrheic dermatitis including itching, scaling, flaking, redness and irritation of the skin. Helps prevent recurrence.

Warnings

For external use only

Ask a doctor before use

- for prolonged periods
- if condition covers a large area of the body
- around the rectum or in the genital area or groin
- with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs

When using this product

avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

- condition worsens
- condition does not improve after regular use of this product as directed.

Use caution in exposing skin to sunlight after applying this product, as it may increase your tendency to sunburn for up to 24 hours after application.

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

Keep out of reach of children.

If swallowed, get medical help or contact a poison control center right away.

Directions

- Read all package directions and warnings before use.
- Use only as directed.
- Apply (gently massage in) a small amount of PSORIASIN to affected areas.

- Apply one to four times daily or as directed by a doctor.
- Apply to thoroughly dry skin.
- The active ingredient, coal tar, in PSORIASIN may affect very light hair color; test first on a small patch of hair before broader application to areas where light colored hair is present.
- Wash affected areas at least daily with mild soap and warm water and dry thoroughly.
- Intended for use by normally healthy adults only.
- Persons under 18 years of age or those with highly sensitive or allergic skin should use only as directed by a doctor.

Other information

You may report serious side effects to the phone number provided under *Questions?* below.

Inactive ingredients

Aloe barbadensis leaf juice, Artemisia mogolia leaf extract, Butylene glycol, Caprylic/capric triglyceride, Caprylyl glycol, Centella asiatica (Gotu kola) extract, Cetareth-20, Cetearyl alcohol, Chlorphenesin, Citric acid, Cocos nucifera (coconut) oil, Disodium EDTA, Ethanol, Ginkgo biloba leaf extract, Glycerin, Glyceryl stearate, Glycyrrhiza glabra (licorice) root extract, Mahonia aquifolium (Oregon grape) extract, Phenoxyethanol, Polysorbate 80, Rosa canina fruit oil, Sodium citrate, Tamarindus indica fruit extract, Vaccinium corymbosum (Blueberry) fruit, Vitamin D3, Water and Zea mays (corn) oil.

Questions?

1-800-792-2582

Psoriasisin.

PROBLEM SKIN FORMULA

CREAM
with Botanicals & Vitamin D3

+NEW

Psoriasisin.

PROBLEM SKIN FORMULA

CREAM
with Botanicals & Vitamin D3

Psoriasisin.

PROBLEM SKIN FORMULA

CREAM
with Botanicals & Vitamin D3

165-ORC,
1217

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CONTAINS NO GLUTEN INGREDIENTS
KEEP TIGHTLY CLOSED WHEN NOT IN USE.
STORE AWAY FROM EXCESSIVE HEAT AND COLD.

Psoriasisin.

PROBLEM SKIN FORMULA

CREAM
with Botanicals & Vitamin D3

With **PSORIASIN LiteTar™†**

- Won't Stain Skin
- No Lingering Odor

Medicated formula penetrates the skin for multi-symptom relief of psoriasis symptoms including itching, flaking, redness, & irritation.

Contains coal tar, the only FDA compliant, non-prescription drug ingredient that slows excessive skin cell production, the root cause of psoriasis symptoms.

www.PSORIASIN.com

† LiteTar is Alva-Amco's trade name for its 0.5% coal tar active ingredient.

Coal tar has been recognized as safe and effective by the FDA, when used as directed.

STOPS PSORIASIS
ITCHING + SCALING + REDNESS

- Steroid & Paraben-Free
- Salicylic Acid-Free
- Dye & Fragrance-Free
- Visible Relief in Just Days

- Restore healthy looking skin and diminish psoriasis symptoms
- Advanced 5-in-1 formula features medicine, multiple moisturizers, plus vitamin D3 and botanicals

#1 OTC PSORIASIS BRAND TREATMENT*



*Based on independent syndicated market research data.

TOPICAL CREAM

NET WT 4 OZ (113 g)

CP-230285
02/2018

Alva-Amco
ALVA-AMCO Pharmaceutical Cos., Inc.
Niles, IL 60714, U.S.A.
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Prod. No.: 1650004

LOT:

EXP:

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PSORIASIN PROBLEM SKIN FORMULA

coal tar cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52389-665
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 g

Inactive Ingredients

Ingredient Name	Strength
ARTEMISIA MONGOLICA LEAF (UNII: WY03A2288R)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
VACCINIUM CORYMBOSUM WHOLE (UNII: G1DGA0BS6T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
CORN OIL (UNII: 8470G57WFM)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TAMARIND JUICE (UNII: 5P6V8403U4)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALCOHOL (UNII: 3K9958V90M)	
GINKGO BILOBA LEAF OIL (UNII: Y5967KO1JH)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAHONIA AQUIFOLIUM FRUITING TOP (UNII: P119855ERN)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52389-665-04	1 in 1 CARTON	04/13/2018	
1		113 g in 1 TUBE; 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	04/13/2018	

Labeler - Alva-Amco Pharmacal Companies, Inc (042074856)

