

EUCUTASOL - coal tar cream
Blaine Labs 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

Active Ingredient

Coal Tar (2%)

Purpose

Purpose

Psoriasis/Seborrheic Dermatitis Treatment

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Uses

Uses

For the relief of symptoms associated with psoriasis and/or seborrheic dermatitis including:

- Itching, scaling, flaking, redness and irritation of the skin
- Treats eczema
- Helps prevent recurrence

Warnings

Warnings

For external use only.

Ask a doctor before use

Ask a doctor before use

If condition covers a large area of the body, around the rectum, in the genital area or the groin. Also, if needed for prolonged periods, or with other forms of psoriasis therapy such as ultra violet radiation or prescription drugs.

Directions

Directions

Apply to affected areas as directed by a doctor.

Other Inactive Ingredients

Other

Dimethicone, Hydrocortisone

Inactive Ingredients

Water, Xanthan Gum, Aloe Vera, Glycerin, Propylene Glycol, Safflower Oil, Dimethicone, C12/15 Alkyl Benzoate, Emulsifying Wax, Glycerol Stearate, Peg 100 Stearate, Cetyl Alcohol, Phenoxyethanol, Methylparaben, Ethylparaben, Butylparaben, Propylparaben, Isobutylparaben, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Hydrocortisone, Triethanolamine, Burdock Root, Tea Tree Oil, Lavender Oil, Chamomile Extract, F.D, and C Yellow # 5

Product label

EuCutaSol

PHYSICIAN FORMULA PSORIASIS TREATMENT Rx

NET WT. 4.0 oz. (112 gr.)

NDC: 63347-301-01

BlaineLabs (800) 307-8818 info@BlaineLabs.com Santa Fe Springs, CA 90670

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| <p>Active Ingredient Purpose</p> <p>Coal Tar (Ph) Psoriasis/Seborrheic Dermatitis Treatment</p> <p>Other</p> <p>Dimethicone, Hydrocortisone</p> <p>Inactive Ingredients</p> <p>Water, Xanthan Gum, Aloe Vera, Glycerin, Propylene Glycol, Safflower Oil, Dimethicone, C12/15 Alkyl Benzoate, Emulsifying Wax, Glycerol Stearate, Peg 100 Stearate, Cetyl Alcohol, Phenoxyethanol, Methylparaben, Ethylparaben, Butylparaben, Propylparaben, Isobutylparaben, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Hydrocortisone, Triethanolamine, Burdock Root, Tea Tree Oil, Lavender Oil, Chamomile Extract, F. D. & C. Yellow # 5</p> <p>Uses</p> <p>For the relief of symptoms associated with psoriasis and/or seborrheic dermatitis including:</p> <ul style="list-style-type: none"> Itching, scaling, flaking, redness and enlargement of lesions Treats eczema Helps prevent recurrence |  <p>NET WT. 4.0 oz. (112 gr.)</p> | <p>Directions</p> <p>Apply to affected areas as directed by a doctor.</p> <p>Warnings</p> <p>For external use only.</p> <p>Ask a doctor before use</p> <p>If condition covers a large area of the body, avoid the neck, in the genital area or the groin. Also, if needed for prolonged periods, or with other forms of systemic therapy such as ultraviolet radiation or psoriasis drugs.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>NDC: 63347-301-02</p> <p>(800) 307-8818 info@BlaineLabs.com Santa Fe Springs, CA 90670</p> |
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| EUCUTASOL | | | |
|--|-------------------|---------------------------|---------------|
| coal tar cream | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63347-301 |
| Route of Administration | TOPICAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | Basis of Strength | Strength | |
| COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC) | COAL TAR | 2 g in 100 g | |
| Inactive Ingredients | | | |
| Ingredient Name | Strength | | |
| WATER (UNII: 059QF0KO0R) | | | |
| XANTHAN GUM (UNII: TTV12P4NEE) | | | |

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| ALOE VERA LEAF (UNII: ZY81Z83H0X) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| SAFFLOWER OIL (UNII: 65UEH262IS) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) |
| PEG-100 STEARATE (UNII: YD01N1999R) |
| CETYL ALCOHOL (UNII: 936JST6JCN) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| METHYL PARABEN (UNII: A2I8C7HI9T) |
| ETHYL PARABEN (UNII: 14255EXE39) |
| BUTYL PARABEN (UNII: 3QPII03FV8) |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) |
| ISOBUTYL PARABEN (UNII: 0QQJ25X58G) |
| POLYACRYLAMIDE (CROSSLINKED; 0.01-0.2 MOLE PERCENT BISACRYLAMIDE) (UNII: RHA9LWJ494) |
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70) |
| LAURETH-7 (UNII: Z95S6G8201) |
| HYDROCORTISONE (UNII: WI4X0X7BPJ) |
| TROLAMINE (UNII: 9O3K93S3TK) |
| ARCTIUM LAPPA ROOT (UNII: 597E9B13Z3) |
| TEA TREE OIL (UNII: VIF565UC2G) |
| LAVENDER OIL (UNII: ZBP1YXW0H8) |
| CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG) |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:63347-301-01 | 112 g in 1 JAR | | |
| 2 | NDC:63347-301-02 | 224 g in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part358H | 07/01/2012 | |

Labeler - Blaine Labs Inc. (017314571)

Registrant - Blaine Labs Inc. (017314571)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|---------|-----------|------------------------|
| Blaine Labs Inc. | | 017314571 | manufacture(63347-301) |

