

ELTA LITE TAR- coal tar lotion lotion
Swiss American Products

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.

Elta Lite Tar

Active Ingredient

Coal Tar 0.8% Psoriasis Relief

Purpose

- Helps eliminate the recurrence of psoriasis on skin and scalp

Indications

- Helps eliminate the recurrence of psoriasis on skin and scalp

Warnings

Helps eliminate the recurrence of psoriasis on skin and scalp

- Keep this and all drugs out of the reach of children.
- If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- apply to affected areas one to four times daily or as directed by a physician.
- Massage in well to affected areas
- for scalp: thoroughly massae into scalp. After one minute, wash out with mild shampoo. Use one time daily or as directed by a physician.

Inactive Ingredients

purified water, petrolatum, alcohol denatured, magnesium aluminum silicate, dea cetyl phosphate, dimethicone, stearic acid, xanthan gum, glyceryl stearate, cetearyl alcohol, polysorbate 60, PEG150 stearate, steareth 20, polyacrylamide, C13-14 isoparaffin, laureth-7, triethanolamine, polysorbate 90, disodium EDTA, phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben, isobutylparaben, fragrance

Questions???

Call 1-800-633-8872

Warning

This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Label

M9882
 6.375" by 5.375"
 PMS 123, PMS 186, BLACK

To: _____

From: _____

EltaLiteTar_8oz-redesign.pdf 1 5/13/14 8:06 AM

NDC 60232-7700-1

Elta® Lite Tar melts into skin on contact for deeper penetration and 8-hour moisturizing power. No greasy, sticky residue or strong odor.

| Drug Facts | |
|--|---|
| Active Ingredient | Purpose |
| Coal Tar 0.8% | Psoriasis Relief |
| Indications | |
| • Helps eliminate the recurrence of psoriasis on skin and scalp. | |
| Warnings | |
| For external use only | |
| 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. Do not use for prolonged periods without consulting a physician. If condition covers a large area of the body, consult your physician before using this product. Do not use this product in or around the rectum or in the genital area or groin except on the advice of physician. If condition worsens or does not improve after regular use of this product as directed, consult a physician. Do not use this product with other forms of psoriasis therapy such as ultraviolet radiation or prescription drugs unless directed to do so by a physician. | |
| Keep this and all drugs out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately. | |
| Directions | |
| • Apply to affected areas one to four times daily or as directed by a physician. Massage in well to affected areas. • For scalp: Thoroughly massage into scalp. After one minute, wash out with mild shampoo. Use one time daily or as directed by a physician. | |
| Inactive ingredients | |
| Purified Water USP, Petrolatum, Alcohol, Denat., Magnesium Aluminum Silicate, DEA Cetyl Phosphate, Dimethicone, Stearic Acid, Xanthan Gum, Glycerol Stearate, Cetearyl Alcohol, Polysorbate 60, PEG-150 Stearate, Steareth 20, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Triethanolamine, Polysorbate 90, Disodium EDTA, Phenoxyethanol, Methylparaben, Ethylparaben, Butylparaben, Propylparaben, Isobutylparaben, Fragrance | |
| Questions? Call 1-800-633-8872 | |
| <small>WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.</small> | |
| Item # 07700 | <small>RM3659 Rev. 5/14</small> |
| Mfd. by Swiss-American Carrollton, TX 75006 elta.net Made in U.S.A. |  <small>N 3 90205 07700 7</small> |



**Psoriasis Relief
Lotion**
(Coal Tar 0.8%)

- 8-hour moisturizing power
- Relieves itching and flaking
- Helps prevent recurrence



8 FL OZ (236 mL)

READ CAREFULLY!

THIS PROOF is sent for an OK of the size, typesetting, layout, and/or the specifications that are marked. It is understood that **you assume the responsibility** for its being read, with errors **plainly marked**. Mark "OK", "OK with alterations" or "Need another proof" on this notice and sign your name. Be sure to return all copy with this proof.

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OK TO PROCEED OK WITH CORRECTIONS REVISED PROOF REQUIRED

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coal tar lotion lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60232-7700 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| COAL TAR (UNII: R533ESO2EC) (COAL TAR - UNII:R533ESO2EC) | COAL TAR | 8 g in 1000 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| WATER (UNII: 059QF0K00R) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) | |
| DIETHANOLAMINE CETYL PHOSPHATE (UNII: 4UG0316V9S) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| PEG-150 STEARATE (UNII: 7BSG7DF10Q) | |
| STEARETH-20 (UNII: L0Q8IK9E08) | |
| POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I) | |
| C13-14 ISOPARAFFIN (UNII: E4F12ROE70) | |
| LAURETH-7 (UNII: Z95S6G8201) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| ETHYLPARABEN (UNII: 14255EXE39) | |
| BUTYLPARABEN (UNII: 3QPII03FV8) | |
| PROPYLPARABEN (UNII: Z8IX2SC10H) | |
| ISOBUTYLPARABEN (UNII: 0QQJ25X58G) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | brown | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:60232-7700-1 | 230 g in 1 BOTTLE, PUMP; 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 | 03/18/2011 | |

Labeler - Swiss American Products (611921669)

Registrant - Swiss American Products (611921669)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|-------------------------|
| Swiss American Products | | 611921669 | manufacture(60232-7700) |

Revised: 8/2015

Swiss American Products