DERMOSCRIBE SEBORRHEIC DERMATITIS- sulfur, salicylic acid, hydrocortisone cream DERMOSCRIBE PTY LTD

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.

DERMOSCRIBE (as PLD) - SEBORRHEIC DERMATITIS CREAM (69683-202)

ACTIVE INGREDIENTS

Sulfur 3%, Salicylic Acid 3%, Hydrocortisone 1%

PURPOSE

TREATMENT OF SEBORRHEIC DERMATITIS.

USE

Dermoscribe's Seborrheic Dermatitis Cream is a topical treatment for relief of the symptoms and signs of Seborrheic Dermatitis.

WARNINGS

FOR EXTERNAL USE ONLY. Avoid contact with mouth, eyes and anal skin. Do not swallow. Seek medical advice before using if pregnant or breastfeeding. If irritation

develops, stop using and seek medical advice. May not be as effective after expiry date.

KEEP OUT OF REACH OF CHILDREN.

DIRECTIONS

For use only by persons over 12 years old. Apply in a thin layer over the affected area once or twice daily as required.

Use only in accordance with the directions on the label and within the packaging. Refer to enclosed leaflet for detailed directions.

INACTIVE INGREDIENTS

AQUEOUS CREAM
STORE AT ROOM TEMPERATURE

DERMO SCRIBE

seborrheic dermatitis

CREAM 2oz Dermoscribe's Seborrheic
Dermatitis Cream is a topical
treatment for relief of the
symptoms and signs of
Seborrheic Dermatitis.

DIRECTIONS: For use by adults and children over 12 years old. Apply a thin layer over the affected area once or twice daily as required. Avoid contact with mouth, eyes and anal skin. Do not swallow. Seek medical advice before using if pregnant or breastfeeding. If irritation develops, stop using and seek medical advice. May not be as effective after expiry date. Use only in accordance with the directions on the label and within the packaging. Refer to enclosed leaflet for detailed directions.

CONTAINS: Sulfur 3%, Salicylic Acid 3%, Hydrocortisone 1%, Aqueous Cream

Made in USA www.dermoscribe.com STORE AT ROOM TEMPERATURE

DERMOSCRIBE SEBORRHEIC DERMATITIS

sulfur, salicylic acid, hydrocortisone cream

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69683-202 |
| Route of Administration | TOPICAL | | |

| Active Ingredient/Active Moiety | | | |
|---|--------------------------|--------------|--|
| Ingredient Name | Basis of Strength | Strength | |
| SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 3 g in 100 g | |
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII: O414PZ4LPZ) | SALICYLIC ACID | 3 g in 100 g | |
| HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE | 1 g in 100 g | |

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) | |

| MINERAL OIL (UNII: T5L8T28FGP) | | |
|--|--|--|
| GLYCOL STEARATE SE (UNII: 6YLY96TQL6) | | |
| SORBITOL (UNII: 506T60A25R) | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | |
| COCONUT OIL (UNII: Q9L0O73W7L) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | | |
| WATER (UNII: 059QF0KO0R) | | |

| Packaging | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:69683-202- 11 | 60 g in 1 BOTTLE; Type 0: Not a Combination Product | 03/23/2015 | |

| Marketing In | arketing Information | | | |
|-------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part348 | 03/23/2015 | | |
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Labeler - DERMOSCRIBE PTY LTD (742164734)

Revised: 10/2023 DERMOSCRIBE PTY LTD