

DERMAD ATOPIC DERMATITIS THERAPEUTIC- salicylic acid cream
Chen Cohen Industries 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.

Drug Facts

Active Ingredient

Salicylic Acid....2%

Purpose

Atopic Dematitis treatment

Uses

Relieves and helps prevent

- itching
- irritation
- redness due to jock itch

Warnings

For external use only

When using this product

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

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply to the affected area one to three times a day or as directed by a doctor.
- Apply on clean and dry skin in circular motion.
- To avoid running or dripping, lightly squeeze the tube.

Other Information

Store between 63°/80°F (17-30C)

Protect from humidity.

Inactive Ingredients



Water, Mineral Oil, Glyceryl Stearate, Cetyl Alcohol, Bees Wax, Sweet Almond Oil, Jojoba Seed Oil, Grape Seed Oil, Decyl Oleate, Hyaluronic Acid, Oeothera Biennis Oil, Calendula Oil, Coconut Oil, Steareth-2, Trictum Vulgaris (Wheat) Germ Oil, Linum Usitatissimum Seed Oil, Butyrospermum Parkii (Shea Butter), Steareth-21, Phenoxyethanol and Triethylene Glycol, Xanthan Gum, BHT, Tocopheryl Acetate, Cannabis Sativa Seed Oil, Farnesol.

Principal Display Panel

NDC 70794-101-28

DERMAD ATOPICE DERMATITIS Therapeutic Cream

RELIEVES

| <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Salicylic Acid 2%</td> <td>Atopic Dermatitis treatment</td> </tr> </tbody> </table> <p>Uses Relieves and helps prevent • Itching • Irritation • redness due to Atopic Dermatitis</p> <p>Warnings For external use only. When using this product • avoid contact with eyes. If contact occurs, rinse eyes thoroughly with lukewarm water. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions • apply to affected area one to three times a day as directed by a doctor. • apply on clean and dry skin in circular motion • to avoid running or dripping, lightly squeeze the tube.</p> <p>Other information store between 63°/86° F (17°-30°C) protect from humidity</p> <p>Inactive Ingredients Water, Mineral Oil, Glyceryl Stearate, Cetyl Alcohol, Bees Wax, Sweet Almond Oil, Jojoba Seed Oil, Grape Seed Oil, Decyl Oleate, Hyaluronic Acid, Oeothera Biennis Oil, Calendula Oil, Coconut Oil, Steareth-2, Trictum Vulgaris (Wheat) Germ Oil, Linum Usitatissimum Seed Oil, Butyrospermum Parkii (Shea) Butter, steareth-21, Phenoxyethanol & Triethylene Glycol, Xanthan Gum, BHT, Tocopheryl Acetate, Cannabis Sativa Seed Oil, Farnesol.</p> | Active ingredient | Purpose | Salicylic Acid 2% | Atopic Dermatitis treatment |  <p>ATOPIC DERMATITIS Therapeutic Cream</p> <p>RELIEVES</p> <ul style="list-style-type: none"> • IRRITATION • ITCHING • REDNESS <p>FDA REGISTERED NDC 70794-101-28</p> <p>DOES NOT CONTAIN STEROIDS, CORTISONE, FRAGRANCES & COLORING</p> <p>2.75 FL.OZ (81mL)</p> | <p>DermaD Atopic Dermatitis Cream is uniquely formulated to relieve the following:</p> <ul style="list-style-type: none"> • Irritation • Itching • Redness • Scaling <p>Made from a unique blend of therapeutic ingredients and infused with Hemp oil, Amino acid, Omega 3,6,9 and antioxidant Vitamin E. Allows for hydration and softening of the skin leaving it nourished and calm.</p> <p>DermaD Atopic Dermatitis Cream is advisable and suitable for people experiencing an Atopic Dermatitis condition.</p> <p>Treatment provides a safe and effective process to relieve and reduce symptoms of areas affected by Atopic Dermatitis.</p> |
|--|-----------------------------|---------|-------------------|-----------------------------|---|---|
| Active ingredient | Purpose | | | | | |
| Salicylic Acid 2% | Atopic Dermatitis treatment | | | | | |
| <p>Distributed By: CRL Ltd 141-18 73rd Terrace Flushing, NY 11367 Derma-D.com Info@derma-d.com</p>  | | | | | | |

- IRRITATION
- ITCHING
- REDNESS

FDA REGISTERED

DOES NOT CONTAIN STEROIDS, CORTISONE, FRAGRANCES AND COLORING

2.75 FL. OZ (81 mL)

DERMAD ATOPIC DERMATITIS THERAPEUTIC

salicylic acid cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70794-101 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ) | SALICYLIC ACID | 20 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| ALMOND OIL (UNII: 66YXD4DKO9) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| GRAPE SEED OIL (UNII: 930MLC8XGG) | |
| DECYL OLEATE (UNII: ZGR06DO97T) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| WHEAT GERM OIL (UNII: 14C97E680P) | |
| STEARETH-2 (UNII: V56DFE46J5) | |
| STEARETH-21 (UNII: 53J3F32P58) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| TRIETHYLENE GLYCOL (UNII: 3P5SU53360) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| FARNESOL (UNII: EB41QIU6JL) | |
| HYALURONIC ACID (UNII: S270N0TRQY) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| LINSEED OIL (UNII: 84XB4DV00W) | |
| CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

| | | | | |
|------------------------------|---|---|-----------------------------|---------------------------|
| 1 | NDC:70794-101-28 | 81 g in 1 TUBE; Type 0: Not a Combination Product | 07/08/2021 | |
| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | | Marketing Start Date | Marketing End Date |
| OTC monograph final | part358B | | 07/08/2021 | |

Labeler - Chen Cohen Industries Inc. (080534875)

Registrant - Chen Cohen Industries Inc. (080534875)

| | | | |
|----------------------|----------------|---------------|----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Peer Pharm Ltd. | | 514678390 | manufacture(70794-101) |

| | | | |
|----------------------|----------------|---------------|----------------------------|
| Establishment | | | |
| Name | Address | ID/FEI | Business Operations |
| Emilia Cosmetics Ltd | | 600076624 | manufacture(70794-101) |

Revised: 11/2021

Chen Cohen Industries Inc.