THERAPLEX AIM ANTI-ITCH MOISTURIZING CREAM- hydrocortisone cream The Theraplex Company, LLC

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.

Theraplex® AIM Anti-Itch Moisturizing Cream

Drug Facts

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

Uses

Temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: •eczema •soaps •detergents •cosmetics •seborrheic dermatitis •psoriasis. •Other uses of this product should only be under the advice and supervision of a doctor.

Warnings

For external use only

- Do not use for the treatment of diaper rash, consult a doctor.
- When using this product, avoid contact with eyes.
- Stop use and ask a doctor if condition worsens, symptoms persist more than 7 days, or clear up and occur again within a few days. Do not begin use of any other hydrocortisone product unless you have asked a doctor.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: do not use, ask a doctor.

Inactive Ingredients

Petrolatum (special fraction), cyclomethicone, coconut oil, microcrystalline wax, ferulic acid, colloidal oatmeal

Other information

• Store at 20° to 25°C (68° to 77°F)

Questions?

 \bullet Toll-free number 888-437-2753 \bullet For more information on Eczema and Theraplex, visit us on our website at www.theraplex.com

NON STINGING

For Maximum Strength Relief of Rashes & Itching Flare-Ups Caused by

• Eczema • Psoriasis • Seborrheic Dermatitis

NEW

Stops the itch of Eczema quickly

- Helps repair and restore the skin's natural protective barrier
- Promotes healthy skin flora
- Contains natural coconut oil to soothe and moisturize the skin
- Instantly penetrates into the skin's surface
- NO preservatives, parabens, fragrances, lanolin, or gluten
- Not tested on animals
- Non-stinging
- Patent Pending

www.theraplex.com

Dist. By The Theraplex Company, LLC, Memphis, TN 38119

Packaging

INNER JAR LABEL







Warnings

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Net Wt. 3 oz. OUTER CARTON LABEL



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DRUG FACTS

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THERAPLEX AIM ANTI-ITCH MOISTURIZING CREAM

hydrocortisone cream

| Product Information | ict Information | | | | | |
|----------------------------|-----------------|--------------------|---------------|--|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62917-819 | | | |
| Route of Administration | TOPICAL | | | | | |

Active Ingredient/Active Moiety Ingredient Name Basis of Strength HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ) HYDROCORTISONE 1 g in 100 g

| Inactive Ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| PETROLATUM (UNII: 4T6H12BN9U) | | | | |
| CYCLOMETHICONE (UNII: NMQ347994Z) | | | | |
| COCONUT OIL (UNII: Q9L0O73W7L) | | | | |
| MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY) | | | | |
| FERULIC ACID (UNII: AVM951ZWST) | | | | |
| OATMEAL (UNII: 8 PI54V663Y) | | | | |

| Packaging | | | | | |
|-----------|------------------|--|----------------------|--------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:62917-819-03 | 1 in 1 CARTON | 08/15/2019 | | |
| 1 | | 85 g in 1 JAR; Type 0: Not a Combination Product | | | |

| Marketing Information | | | | | | |
|-------------------------|--|----------------------|--------------------|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | |
| OTC monograph not final | part348 | 08/15/2019 | | | | |
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Labeler - The Theraplex Company, LLC (363529392)

Revised: 6/2019 The Theraplex Company, LLC