

**TRUELIPIDS 1% HYDROCORTISONE BARRIER CREAM- hydrocortisone cream  
Claridei Laboratories**

*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.*

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**TrueLipids 1% Hydrocortisone Barrier Cream**

Active Ingredient.....Purpose

Hydrocortisone 1% .....Anti-itch

**Uses**

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
- eczema
- psoriasis
- poison ivy, oak, sumac
- insect bites
- detergents
- soaps
- cosmetics
- jewelry
- seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

**Keep out of reach of children.**

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

**Stop use and ask a doctor if**

- condition worsens
- rectal bleeding occurs
- 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

**Warnings**

**For external use only**

**Do not use**

- in the genital area if you have a vaginal discharge. consult a doctor
- for the treatment of diaper rash. consult a doctor

**when using this product**

avoid contact with eyes

do not use more than directed unless told to do so by a doctor

do not put directly into rectum by using fingers or any mechanical device or applicator

### **Directions**

- **for itching of skin irritation, inflammation and rashes:**
  - adults and children 2 years of age and older: apply to affected area not more than 3-4 times daily
  - children under 2 years of age: ask a doctor
  - **for external anal and genital itching adult:**
    - when practical clean the affected area with mild soap and water and rinse thoroughly
  - gently dry by patting or blotting with toilet tissue or a soft cloth before applying

### Inactive ingredients

Water, Caprylic/capric Triglyceride, Petrolatum, Neopentyl Glycol Diheptanoate, Glyceryl Stearate, Polyglyceryl-2 Stearate, Isostearyl Isostearate, Cetyl Alcohol, Propanediol (from Corn) , Glycerin, Stearyl Alcohol, Euphorbia Cerifera (Candelilla Wax), C10-30 Cholesterol/Lanosterol Esters, Potassium Stearate, Glycyrrhetic Acid (from Licorice root), Glyceryl Distearate, Stearic Acid, Caprylyl Glycol, Xanthan Gum, Niacinamide, 1,2-Hexanediol, Phytospingosine, Disodium EDTA, Ceramide NP, Tocopherol

### Other information

store at 20°-25°C (68°-77°F)

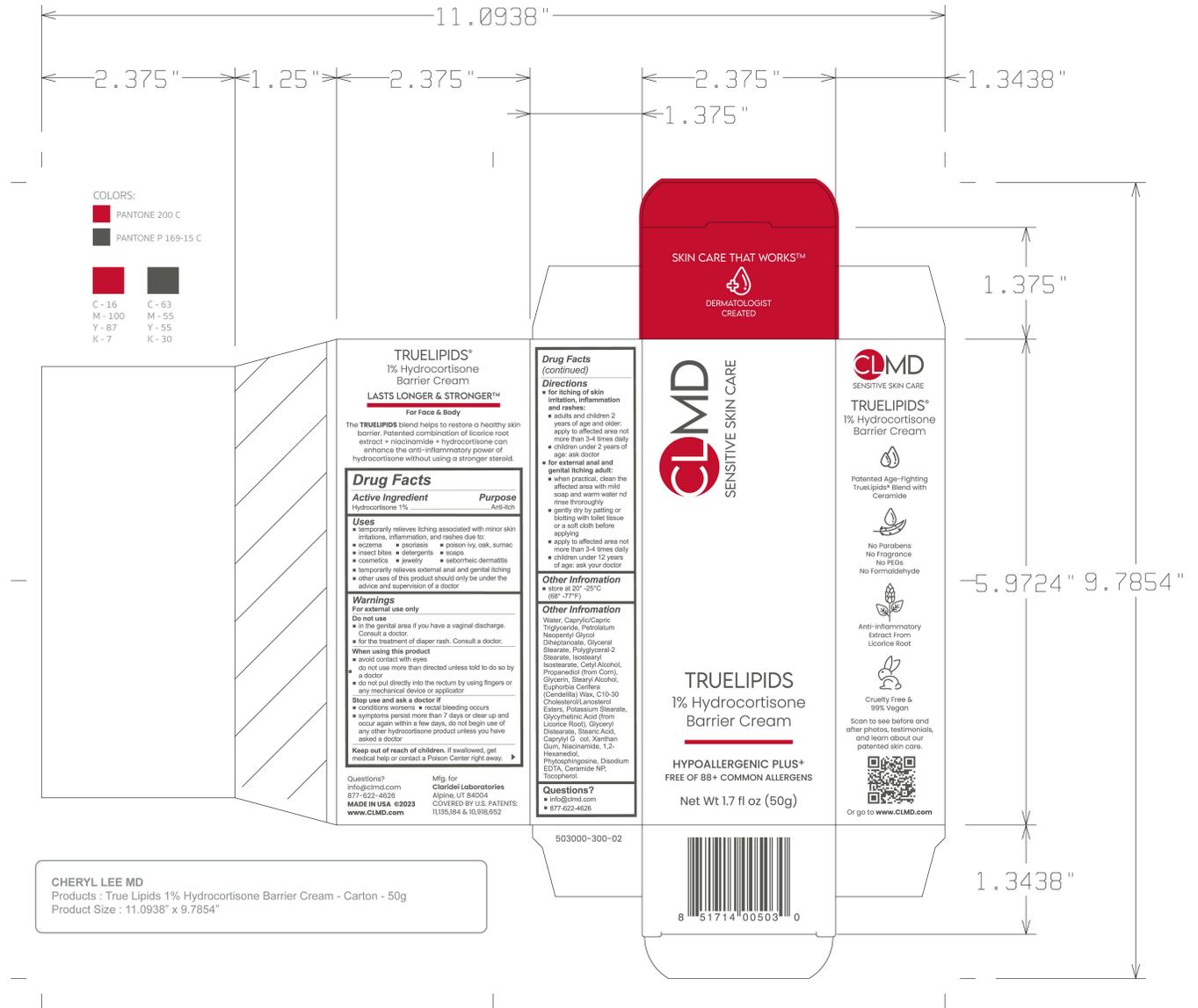
CLMD

Sensitive Skin Care

True Lipids

1% Hydrocortisone Barrier Cream

Net Wt 1.7 fl oz (50g)



| TRUELIPIDS 1% HYDROCORTISONE BARRIER CREAM |  |                           |                 |
|--|--|---------------------------|-----------------|
| hydrocortisone cream                       |  |                           |                 |
| Product Information                        |  |                           |                 |
| <b>Product Type</b>                        | HUMAN OTC DRUG   | <b>Item Code (Source)</b> | NDC:61387-252   |
| <b>Route of Administration</b>             | TOPICAL  |                           |                 |
| Active Ingredient/Active Moiety            |  |                           |                 |
|  | <b>Ingredient Name</b>   | <b>Basis of Strength</b>  | <b>Strength</b> |
|  | HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE            | 1 g in 100 g    |
| Inactive Ingredients                       |  |                           |                 |
|  | <b>Ingredient Name</b>   | <b>Strength</b>           |                 |
|  | MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)                      |                           |                 |

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| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                           |
| <b>POLYGLYCERYL-2 STEARATE</b> (UNII: 253MC0P0YV)              |
| <b>CANDELILLA WAX</b> (UNII: WL0328HX19)                       |
| <b>POTASSIUM STEARATE</b> (UNII: 17V812XK50)                   |
| <b>ENOXOLONE</b> (UNII: P540XA09DR)                            |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                         |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)                |
| <b>C10-30 CHOLESTEROL/LANOSTEROL ESTERS</b> (UNII: 137SL7ILOY) |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)                      |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4)                          |
| <b>PHYTOSPHINGOSINE</b> (UNII: GIN46U9Q2Q)                     |
| <b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)           |
| <b>PETROLATUM</b> (UNII: 4T6H12BN9U)                           |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                             |
| <b>GLYCERYL DISTEARATE</b> (UNII: 73071MW2KM)                  |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                          |
| <b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)                       |
| <b>CERAMIDE NP</b> (UNII: 4370DF050B)                          |
| <b>ISOSTEARYL ISOSTEARATE</b> (UNII: IV0Z586Z4Y)               |
| <b>WATER</b> (UNII: 059QF0KO0R)                                |
| <b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)        |
| <b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)                      |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)                        |
| <b>PROPANEDIOL</b> (UNII: 5965N8W85T)                          |

### Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61387-252-01 | 50 g in 1 TUBE; Type 0: Not a Combination Product | 08/10/2023           |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348                                  | 08/10/2023           |                    |

**Labeler** - Claridei Laboratories (035627639)