

# DERMACHANGE COLD THERAPY- menthol gel

## Private Label Beauty and Wellness

### Dermachange Cold Therapy Gel, Menthol 2%

Menthol 2%

Topical Analgesic

For the temporary relief of minor aches and pains associated with arthritis, simple backache, strains, sprains, and bruises.

#### For external use only.

**Do not use** with other topical pain relievers, with heating pad or heating devices.

**When using this product** do not use in or near the eyes, do not apply to wounds or damaged skin, do not bandage tightly.

**Stop use and ask a doctor if** condition worsens, symptoms last more than 7 days or clear and occur again within a few days.

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

- adults and children 12 years and older, apply to affected area not more than 3 to 4 times daily.
- Children under 12 years old, ask a doctor

Ammonium hydroxide, blue 1, carbomer, copper PCA, isopropyl alcohol, magnesium sulfate, sodium hydroxide, thymol, water.

**Drug Facts**  
**Active ingredient** Menthol 2%  
**Purpose** Topical Analgesic  
**Uses** For the temporary relief of minor aches and pains of muscles associated with:  
 • arthrits  
 • simple backache  
 • strains  
 • sprains  
**Warnings**  
 For external use only.  
 • Do not use with other topical pain relievers.  
 • Do not use with heating pads or heating devices.  
**When using this product**  
 • do not use in or near the eyes  
 • do not apply to wounds or damaged skin  
 • do not bandage tightly  
 Stop use and ask a doctor if:  
 • condition worsens  
 • symptoms persist for more than 7 days or clear up and occur again within a few days.  
**Directions**  
 For adults and children 12 years or older: apply to affected area not more than 3 to 4 times daily.  
 For children under 12 years of age: ask a doctor.  
**Inactive ingredients** ammonium hydroxide, blue 1, carbomer, copper PCA, isopropyl alcohol, magnesium sulfate, sodium hydroxide, thymol, water.  
 Distributed by:  
 Private Label Beauty & Wellness  
 10900 US Highway 19 North, Clearwater, FL 33764 USA  
 323-770-1555  
 8 50040 13856 6  
 NEW Dermachange Cold Therapy Gel (Net Wt 8 oz (227 g))

**dermachange**  
 THE SCIENCE OF NATURE  
**COLD THERAPY GEL**  
 Fast-Acting and Long-Lasting Comfort  
 Greaseless • Therapeutic  
 NET WT 8 OZ (227 g)

## DERMACHANGE COLD THERAPY

menthol gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:83520-131 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength     |
|--|-------------------|--------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL           | 2 g in 100 g |

## Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>AMMONIA</b> (UNII: 5138Q19F1X)  |          |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)  |          |
| <b>WATER</b> (UNII: 059QF0KO0R)  |          |
| <b>CARBOMER INTERPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 132584PQMO) |          |
| <b>COPPER PIDOLATE</b> (UNII: 497G7G1SL1)  |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)   |          |
| <b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)                              |          |
| <b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)  |          |
| <b>THYMOL</b> (UNII: 3J50XA376E)   |          |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)   |          |

## Packaging

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:83520-131-08 | 227 g in 1 JAR; Type 0: Not a Combination Product | 10/27/2023           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M017                                     | 10/27/2023           |                    |

**Labeler** - Private Label Beauty and Wellness (035014854)

**Registrant** - Derma Care Research Labs, LLC (116817470)

## Establishment

| Name                          | Address | ID/FEI    | Business Operations    |
|-------------------------------|---------|-----------|------------------------|
| Derma Care Research Labs, LLC |         | 116817470 | manufacture(83520-131) |

Revised: 3/2024

Private Label Beauty and Wellness