# MENTHOL PAIN RELIEVING CREAM WITH MENTHOL 10%- menthol 10% cream cream ONE2ZEE LIMITED LIABILITY COMPANY

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Menthol Pain Relieving Cream - Menthol 10%

**DRUG FACTS:** 

#### **Active Ingredient:**

Menthol 10%

#### **Purpose**

Pain relieving cream

#### **Uses:**

Temporarily relieves minor aches and pains of muscles and joints associated with:

- simple
- backache
- arthritis
- strains
- bruises
- sprains

## **Warnings:**

• **For external use only**. If condition worsens or does not improve within 7 days, consult a doctor.

# When using this product,

- use only as directed
- avoid contact with the eyes or on mucous membranes
- do not apply to wounds or damaged skin
- do not apply to irritated skin or if excessive irritation develops
- do not bandage tightly or use with heating pad or device

#### **Directions:**

- adults and children 12 years of age and older: rub a thin film over affected area not more than 3 to 4 times daily
- children under 12 years of age: consult a physician
- wash hands after use with cool water

Adults and children 12 years and older: For optimum results cleanse the affected

area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a clean, soft cloth before application of this product. Apply externally up to 6 times per day.

#### Keep out of reach of children.

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

#### **Inactive Ingredients**

Caprylic/Capric Triglyceride, Cetearyl Alcohol, Diazolidinyl Urea, Dimethicone, Gluconolactone, Glycerin, Glyceryl Stearate, Ilex Paraguariensis Leaf Extract, Iodopropynyl Butylcarbamate, Polysorbate 60, Sodium Benzoate, Sodium Hydroxide, Sodium Stearoyl Lactylate, Tetrasodium EDTA, Tocopheryl Acetate, Vitis Vinifera (Grape) Seed Oil, Water

#### Other Information:

store at 20-25°C (68-77°F) ☐ store in a cool dry place away from direct sunlight

### Package Label



#### MENTHOL PAIN RELIEVING CREAM WITH MENTHOL 10% menthol 10% cream cream **Product Information Product Type** HUMAN OTC DRUG Item Code (Source) NDC:55629-018 **Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength** Strength MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL 0.1 g in 1 g

| Inactive Ingredients                               |          |  |  |  |
|--|----------|--|--|--|
| Ingredient Name                                    | Strength |  |  |  |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)             |          |  |  |  |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)               |          |  |  |  |
| DIMETHICONE (UNII: 92RU3N3Y1O)                     |          |  |  |  |
| GLUCONOLACTONE (UNII: WQ29KQ9POT)                  |          |  |  |  |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                 |          |  |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                        |          |  |  |  |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)           |          |  |  |  |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F)        |          |  |  |  |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)      |          |  |  |  |
| WATER (UNII: 059QF0KO0R)                           |          |  |  |  |
| POLYSORBATE 60 (UNII: CAL22UVI4M)                  |          |  |  |  |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)                |          |  |  |  |
| SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)       |          |  |  |  |
| TETRASODIUM EDTA (UNII: MP1J8420LU)                |          |  |  |  |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)        |          |  |  |  |
| VITIS VINIFERA (GRAPE) SEED OIL (UNII: 930MLC8XGG) |          |  |  |  |

| l | Packaging |                      |   |                         |                       |  |  |
|---|-----------|----------------------|---|-------------------------|-----------------------|--|--|
|   | #         | Item Code            | Package Description                               | Marketing Start<br>Date | Marketing End<br>Date |  |  |
|   | 1         | NDC:55629-018-<br>05 | 141 g in 1 JAR; Type 0: Not a Combination Product | 04/21/2025              |                       |  |  |

| Marketing Information |   |                         |                       |  |  |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| OTC Monograph Drug    | M   | 04/21/2025              |                       |  |  |
|                       |   |                         |                       |  |  |

# Labeler - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

**Registrant -** ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Revised: 5/2025 ONE2ZEE LIMITED LIABILITY COMPANY