**PROZERO- menthol gel**
**RLABS, 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.*

---

**ACTIVE INGREDIENT**

MENTHOL 5%

**PURPOSE**

TOPICAL ANALGESIC

**USES**

Temporarily relieves minor aches and pains of arthritis, simple backache, muscle strains, sprains, bruises, and cramps.

**WARNINGS**

FOR EXTERNAL USE ONLY

When using this product: •Use only as directed. Read and follow all directions and warnings on this label. •Do not use with other sprays, ointments, creams, or liniments. •Do not bandage or apply local heat (such as heating pads) or medicated patches to the area of use. •Avoid contact with eyes and mucous membranes. •Do not apply to wounds or damaged, broken or irritated skin. •A transient burning sensation may occur upon application but generally disappears in several days. •Rare cases of serious burns have been reported
with products of this type.

Stop use and consult a doctor if: •condition worsens •redness is present •irritation develops •symptoms persist for more than 7 days, or clear up and occur again within a few days •you experience signs of skin injury, such as pain, swelling, or blistering where the product is applied.

If pregnant or breast-feeding, consult a healthcare professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. Store in a cool, dry place with the cap closed tightly and keep away from excessive heat or open flame.

**DIRECTIONS**

Adults and children over 12 years: •Apply a thin layer to affected area.
•Massage into painful area until thoroughly absorbed into skin.
•AFTER APPLYING, WASH HANDS WITH SOAP AND WATER.
Children 12 years or younger: Consult a doctor.

**INACTIVE INGREDIENTS**

Aloe Barbadensis Leaf Juice, Alcohol Denat., Arnica Montana Flower Oil, Propylene Glycol, Eucalyptus Globulus Leaf Oil, Mentha Arvensis (Horsemint) Leaf Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Glucosamine, Dimethyl Sulfone, Tocopheryl Acetate, Lantana Camara (Sage)

Leaf Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Thymus Serpillum (Thyme) Leaf Extract, Glycereth-2 Cocoate, Pyridoxine HCL, Dimethylamino Methylpropanol, Benzoic Acid, Ethylhexylglycerin, Phenoxyethanol, CI 42090 (BLUE 1)


**PROZERO**

menthol gel

**Product Information**

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:70585-111 |
| **Route of Administration** | TOPICAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **MENTHOL** (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 5 g in 100 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **ARNICA MONTANA FLOWER** (UNII: OZ0E5Y15PZ) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **EUCALYPTUS GLOBULUS LEAF** (UNII: S546YLW6E6) | |
| **MENTHA ARVENSIS LEAF OIL** (UNII: 1AEY1M553N) | |
| **CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)** (UNII: 59TL3WG5CO) | |
| **GLUCOSAMINE** (UNII: N08U5BOQ1K) | |
| **DIMETHYL SULFONE** (UNII: 9H4PO4Z4FT) | |
| **.ALPHA.-TOCOPHEROL ACETATE** (UNII: 9E8X80D2L0) | |
| **LANTANA CAMARA LEAF** (UNII: 90ZS0N560Y) | |
| **ROSMARINUS OFFICINALIS WHOLE** (UNII: EA3289138M) | |
| **THYMUS SERPYLLUM** (UNII: 86H4S6K51N) | |
| **GLYCERETH-2 COCOATE** (UNII: JWM00VS7HC) | |
| **PYRIDOXINE HYDROCHLORIDE** (UNII: 68Y4CF58BV) | |
| **DIMETHYLAMINE** (UNII: ARQ8157E0Q) | |
| **BENZOIC ACID** (UNII: 8SKN0B0MIM) | |
| **ETHYLHEXYLGLYCERIN** (UNII: 147D247K3P) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:70585-111-05 | 5 mL in 1 TUBE; Type 0: Not a Combination Product | 08/09/2016 | |
| **2** | NDC:70585-111-34 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 08/09/2016 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 08/09/2016 | |

## Labeler - RLABS, LLC (080198106)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| HEALTHSPECIALTY | | 794053863 | manufacture(70585-111) |

Revised: 1/2020 RLABS, LLC