**FROZEN ICE FAST PAIN RELIEF- menthol camphor (natural) gel**
**GADAL Laboratories, Inc**

*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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**Gadaderm Frocen Ice FastmPain Releive**

## ACTIVE INGREDIENT

| Active Ingredients | Purpose |
|---|---|
| Menthol 3.5% | Topical Analgesic |
| Camphor 0.2% | Topical Analgesic |

## INACTIVE INGREDIENT

Carbomer, Propylene Glycol, Methylparaben, Isopropyl Alcohol, Triethanolamine, FD&C Blue #1, Purified Water.

## KEEP OUT OF REACH OF CHILDREN

KEEP THIS AND ALL MEDICINE OUT OF REACH OF CHILDREN

## WARNINGS

For the external use only. Use only as directed.

- If condition worsens, or if symptoms persist for more than 7 days or clear up and occurs again within a few days, discontinue use of this product and consults a doctor.
- Avoid contact with eyes.
- Do not use with other topical products.
- Do not use with heating device.
- Do not apply to open wounds or damaged skin.

In case of accidental ingestion, seek professional help and contact a Poison Control Center immediately.

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

## DOSAGE & ADMINISTRATION

Adults and children 12 years of age and older.
Apply to painful muscles and joints.
Gently massage thoroughly into affected area.
Repeat as necessary but no more than 4 times daily

## PURPOSE

Topical Analgesic

**Other Information:**

Store in cool, dry location at room temperature 59°- 86°F (15° - 30°C) with cao closed tightly. Keep away from excessive heat or open flame.

Manufactured by:

GABAL Laboratories, Inc.

Miami, FL 33186 – (305)382-3288

www.gadallaboratories.com

MADE IN USA

**FROZEN ICE FAST PAIN RELIEF**


## FROZEN ICE FAST PAIN RELIEF

menthol camphor (natural) gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:53113-363 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MENTHOL** (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 3.5 g in 100 mL |
| **CAMPHOR (NATURAL)** (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 0.2 g in 100 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CARBOXYPOLYMETHYLENE** (UNII: 0A5MM307FC) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |
| **TROLAMINE** (UNII: 9O3K93S3TK) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **WATER** (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:53113-363-03 | 89 mL in 1 APPLICATOR; Type 0: Not a Combination Product | 11/01/2016 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 11/01/2016 | |

## Labeler - GADAL Laboratories, Inc (841305639)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| GADAL Laboratories, Inc | | 841305639 | MANUFACTURE(53113-363) |

Revised: 11/2016 GADAL Laboratories, Inc