# ARCTIC ICE- menthol gel BLUE CROSS 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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#### **ARCTIC ICE Pain Relieving Gel**

#### **Active Ingredient:**

Menthol, 2 percentage

#### **Purpose**

Topical analgesic

#### **Uses:**

Temporarily relieves:

minor muscle aches and pains

#### **Warnings:**

For external use only; avoid contact with eyes. Ask a doctor before use if you have cough associated with

smoking, excessive phlegm, asthma, emphysema, persistent or chronic cough

#### When using this product, do not:

heat

microwave

add to hot water or any container where heating water may cause splattering and result in burns

use in eyes or directly on mucous membranes

take by mouth or place in nostrils

apply to wounds or damaged skin

bandage skin

#### Consult a doctor and discontinue use:

if condition worsens, persists for more than 1 week or tends to recur.

#### Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

#### **DIRECTIONS:**

For the temporary relief of minor muscle aches and pains.

See important warnings under "When using this product"

- not for use on children under 2 years of age
- adults & children 2 years & older: Apply liberally to painful area and massage until gel is absorbed into the skin. Repeat 3 to 4 times daily.

#### **Inactive Ingredients:**

Blue 1, Camphor, Carbomer, Isopropyl Alcohol, Methylchoroisothiazolinone, Methylisothiazolinone, Sodium Hydroxide, Water.

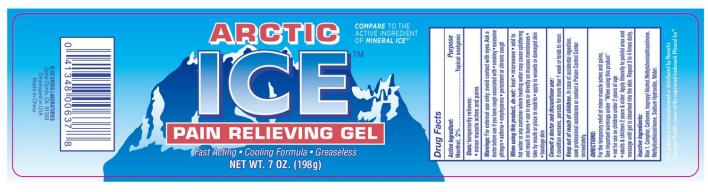
Arctic Ice Pain Relieving Gel

Fast acting Cooling Formula Greaseless

NET. WT. 6 oz. (170g)

419221 (00221) Arctic Ice (197x38mm)





# ARCTIC ICE menthol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:22431-022

#### **Route of Administration**

**TOPICAL** 

| Active | Ingredient/Active | Moiety |
|--------|-------------------|--------|
|--------|-------------------|--------|

| - 10 111 g. 0 111 g. 10 11 g. 10 11 g. 10 11 g. 1      |                          |              |
|--|--------------------------|--------------|
| Ingredient Name  | <b>Basis of Strength</b> | Strength     |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL                  | 2 g in 100 g |

| Inactive Ingredients                           |          |  |
|--|----------|--|
| Ingredient Name                                | Strength |  |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)       |          |  |
| WATER (UNII: 059QF0KO0R)                       |          |  |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)             |          |  |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)         |          |  |
| ISOPROPYL ALCOHOL (UNII: ND2M416302)           |          |  |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) |          |  |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)            |          |  |
| CARBOMER 934 (UNII: 7135WT9208)                |          |  |

| P | Packaging            |  |                         |                       |  |
|---|----------------------|--|-------------------------|-----------------------|--|
| # | Item Code            | Package Description                                  | Marketing Start<br>Date | Marketing End<br>Date |  |
| 1 | NDC:22431-022-<br>01 | 198 g in 1 BOTTLE; Type 0: Not a Combination Product | 10/01/2020              |                       |  |
| 2 |                      | 170 g in 1 BOTTLE; Type 0: Not a Combination Product | 05/03/2022              |                       |  |

| Marketing Information   |   |                         |                       |
|-------------------------|---|-------------------------|-----------------------|
| Marketing<br>Category   | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC monograph not final | part348                                     | 10/01/2020              |                       |
|                         |   |                         |                       |

## Labeler - BLUE CROSS LABORATORIES, INC. (008298879)

### **Registrant -** BLUE CROSS LABORATORIES, INC. (008298879)

Revised: 5/2022 BLUE CROSS LABORATORIES, INC.