

ARCTIC ICE ANALGESIC- 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.

ARCTIC ICE ANALGESIC GEL

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Active Ingredient

Menthol 1.0%

Purpose

Topical Analgesic

Uses

Temporary relief:

minor muscles 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, persist 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 and children 2 years of age and older: apply to painful area and massage until gel is absorbed into the skin, repeat 3 to 4 times daily

Inactive Ingredients

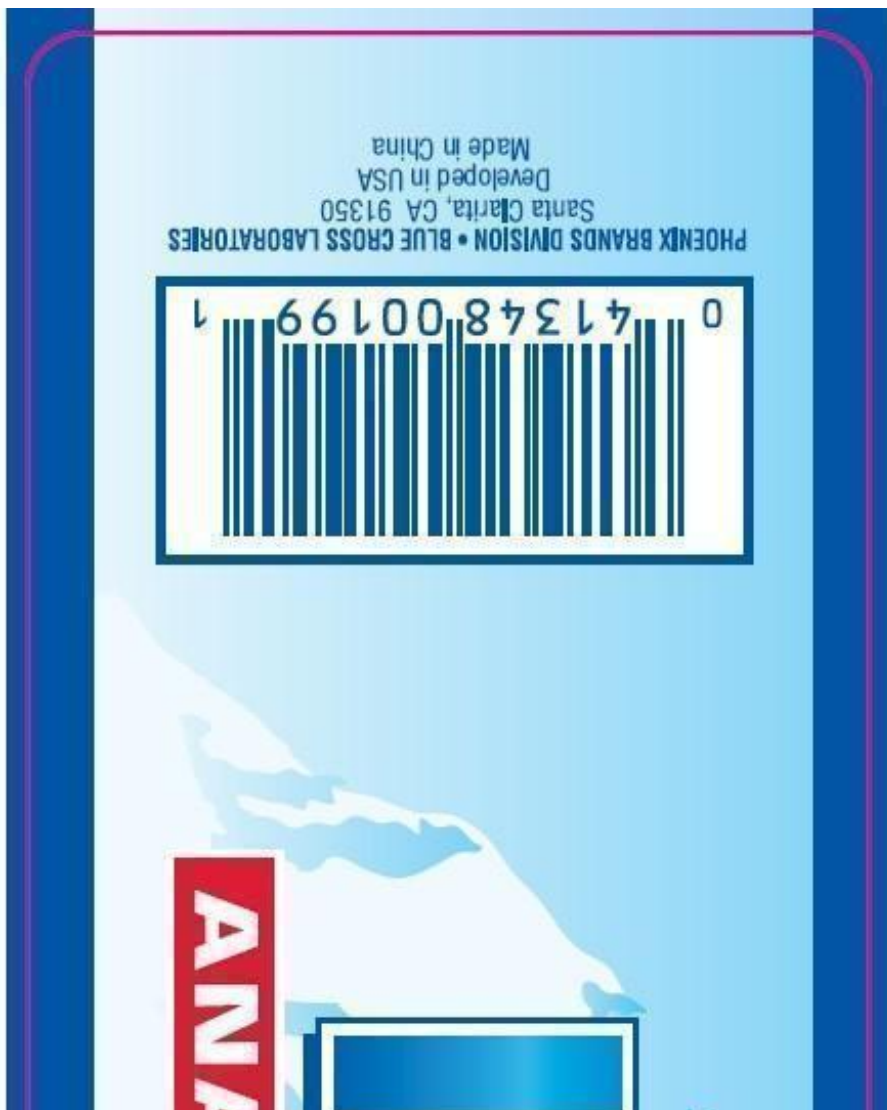
blue 1, camphor, carbomer, isopropyl alcohol, methylchloroisothiazolinone, methuyliothiazoline, sodium hydroxide, water

Principle display panel

Arctic Ice

Analgesic Gel

Net Wt. 8 oz. (227g)



ARCTIC



ALGESIC GEL

NET WT. 8 OZ. (227g)

Drug Facts

| <i>Active Ingredient:</i> | <i>Purpose</i> |
|---------------------------|-------------------|
| Menthol, 1.0%..... | 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:

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, Methylchloroisothiazolinone, Methylisothiazolinone, Sodium Hydroxide, Water.

ARCTIC ICE ANALGESIC

menthol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:22431-012 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 1.0 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| CAMPHOR (NATURAL) (UNII: N20HL7Q941) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| METHYLCHLOROISOETHIAZOLINONE (UNII: DEL7T5QRPN) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:22431-012-01 | 227 g in 1 JAR; Type 0: Not a Combination Product | 12/11/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC mono graph not final | part348 | 12/11/2015 | |

Labeler - Blue Cross Laboratories, Inc. (008298879)

Registrant - Ningbo Liyuan Daily Chemical Products Co., Ltd (530766098)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| Ningbo Liyuan Daily Chemical Products Co., Ltd | | 530766098 | manufacture(22431-012) |

Revised: 12/2019

Blue Cross Laboratories, Inc.