

ARCTIC ICE PAIN RELIEVING- 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 pain relieving gel

ARCTIC ICE ANALGESIC GEL

Active Ingredient

Menthol 2.0%

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, methylchoroisothiazolinone, methuylisothiazoline, sodium hydroxide, water



ARCTIC ICE

COMPARE TO THE
ACTIVE INGREDIENT
OF MINERAL ICE®*



TM

PAIN RELIEVING GEL

Fast Acting • Cooling Formula • Greaseless

NET WT. 8 OZ. (227g)

Drug Facts

Active Ingredient:

Menthol, 2%

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, Methylchlorisothiazolinone, Methylisothiazolinone, Sodium Hydroxide, Water.

*This product is not manufactured or distributed by Novartis Consumer Health, owner of the registered trademark Mineral Ice®.

ARCTIC ICE PAIN RELIEVING

menthol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:22431-014 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 2 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) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:22431-014-01 | 1 in 1 PACKAGE | 02/23/2017 | |
| 1 | | 227 g in 1 JAR; Type 0: Not a Combination Product | | |
| 2 | NDC:22431-014-02 | 1 in 1 PACKAGE | 11/11/2020 | |
| 2 | | 198 g in 1 JAR; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 02/23/2017 | |

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(22431-014) |

Revised: 11/2022

Blue Cross Laboratories, Inc.