

**BLUE ICE- menthol gel**  
**JT Cosmetics and Chemicals**

*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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**BLUE ICE**

Diva Blue Ice is a cool, greaseless pain reliever. It penetrates deep into skin for fast, temporary relief of minor aches and pains in muscles and joints. It provides cooling, soothing relief that lasts for hours.

***Drug Facts***

**Active Ingredients**

Menthol 2%

**Purpose**

Topical Analgesic

**Keep out of reach of children.**

**Usage:**

Provides temporary relief of minor aches and pains in muscles and joints associated with simple backache, strains, sprains, arthritis and sports injuries.

**Warning**

**For External use only. Not for internal use.**

Use only as directed. Avoid contact with eyes or mucous membranes. Do not apply to open wounds or damaged skin. Make sure skin is clean and free from any creams, ointments, sprays or liniment. Do not bandage.

**Do not use with heating pads or heating devices.**

If condition worsens or symptoms persist for more than 7 days or if symptoms disappear and occur again within a few days, discontinue use and consult a physician. If you have sensitive skin, consult a physician before use. If skin irritation develops, discontinue use and consult a physician. If you are pregnant or nursing a baby, consult your doctor before use.

**Direction**

Clean skin of all other lotions, cream ointments, liniment or sprays. Apply liberally to affected area and massage until gel is absorbed into skin. Do not apply more than 3 or 4 times daily. No protective cover needed. Do not apply to children under 2 years of age.

**Inactive Ingredients:**

Water, Isopropyl Alcohol, Camphor, Carbomer, Sodium Hydroxide, Methylchloroisothiazolinone & Methylisothiazolinone, Blue 1 (CI 42090).

Do not use, store, pour or spill near heat or open flame. Store in a cool, dry place and keep lid tightly

closed.

**Distributed by**

**JMD ALL STAR IMPEX INC.,**

**Edison, NJ - 08817**

Made in India.

Neutral Code : GUJ/GA/1676

## Packaging

### FRONT PANEL

Mfg Dt :      Batch No :      Exp Dt :

**DIVA'S**  
**BLUE ICE**  
*Soothing Analgesic Gel*

Fast, Temporary relief from muscle aches and pains  
● greasless ● analgesic ● Net Wt. 8 Oz (227g)

Diva Blue Ice is a cool, greasless pain reliever. It penetrates deep into skin for fast, temporary relief of minor aches and pains in muscles and joints. It provides cooling, soothing relief that lasts for hours.

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| <b>Drug Facts</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Active Ingredients</b><br>Menthol 2%      Topical Analgesic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
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| <b>Inactive Ingredients:</b><br>Water, Isopropyl Alcohol, Camphor, Carbomer, Sodium Hydroxide, Methychloroisothiazolinone & Methisothiazolinone, Blue 1 (CI 42090).                                                                                                                                                                                                                                                                                                                                                                                      |

AS978A  
Distributed by:  
JMD ALL STAR IMPEX, INC.,  
Edison, NJ - 08817  
NDC: 169853-002-76  
Neutral Code:  
GUJ/GA/1676

### DRUG FACTS LABELING

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**BLUE ICE**

menthol gel

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:69859-002 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>                                                   | <b>Basis of Strength</b>  | <b>Strength</b> |
|--------------------------------------------------------------------------|---------------------------|-----------------|
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 2 g in 100 g    |

**Inactive Ingredients**

| <b>Ingredient Name</b>                          | <b>Strength</b> |
|-------------------------------------------------|-----------------|
| WATER (UNII: 059QF0KO0R)                        |                 |
| ISOPROPYL ALCOHOL (UNII: ND2M416302)            |                 |
| CAMPHOR (NATURAL) (UNII: N20HL7Q941)            |                 |
| CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E) |                 |
| SODIUM HYDROXIDE (UNII: 55X04QC32I)             |                 |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)  |                 |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)        |                 |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)              |                 |

**Packaging**

| # | <b>Item Code</b> | <b>Package Description</b>                        | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---|------------------|---------------------------------------------------|-----------------------------|---------------------------|
| 1 | NDC:69859-002-76 | 227 g in 1 JAR; Type 0: Not a Combination Product |                             |                           |

**Marketing Information**

| <b>Marketing Category</b> | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|---------------------------|-------------------------------------------------|-----------------------------|---------------------------|
| OTC monograph not final   | part348                                         | 05/23/2015                  |                           |

**Labeler** - JT Cosmetics and Chemicals (650884849)**Establishment**

| <b>Name</b>                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
|----------------------------|----------------|---------------|----------------------------|
| JT Cosmetics and Chemicals |                | 650884849     | manufacture(69859-002)     |

Revised: 6/2015

JT Cosmetics and Chemicals