

BLUE ICE - menthol gel
JMD All Star Impex 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.

Active Ingredient

Menthol 2.0%

Purpose

External pain reliever

Uses

Temporary relief of minor pains of muscles and joints associated with

- Simple back ache
- Arthritis
- Sprains, strains or bruises

Warning

For external use only. Avoid contact with eyes

Do not use

- Internally
- With heating pads or devices
- On wounds or damaged skin

Ask doctor before use if you have sensitive skin

When using this product

- Use only as directed
- Do not bandage tightly
- Avoid contact with eyes and mucus membranes

If pregnant or breast feeding, ask a health professional before use

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center immediately

Direction

- Adult and children 2 years of age and older. Clean skin thoroughly. Apply liberally to affected area not more than 3-4 times daily. No protective cover needed.
- May be used with ice packs
- May be used with wet or dry bandage, but wrap loosely
- Children under 2 years of age, consult a doctor

Other Information store between 59-85F (15-30C)

- Keep tightly closed
- Do not use, pour, spill or store near heat or open flames

Other Ingredients Carbomer 940, FDC Blue No. 1, Isopropyl Alcohol, Propylene Glycol, Purified Water, Sodium Hydroxide,

Package Label



Drug Facts

Active Ingredients

Menthol 2 %External pain reliever

Purpose

Uses Temporary relief of minor pains of muscles and joints associated with

- Simple back ache
 - Arthritis
 - Sprains ,strains or bruises
-

Warning

For external use only. Avoid contact with eyes

Do not use

- Internally
 - With heating pads or devices
 - On wounds or damaged skin
-

Ask doctor before use if you have sensitive skin

When using this product ■ Use only as directed ■ Do not bandage tightly

- Avoid contact with eyes and mucus membranes
-

If pregnant or breast feeding, ask a health professional before use

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a poison Control Center immediately

Direction

- Adult and children 2 years of age and older .Clean skin thoroughly .Apply liberally to affected area not more than 3-4 times daily .No protective cover needed ■ May be used with ice packs
 - May be used with wet or dry bandage , but wrap loosely ■ Children under 2 years of age ,consult a doctor
-

Other Information store between 59 – 85°F (15-30°C) ■ Keep tightly closed

- Do not use , pour ,spill or store near heat or open flames
-

Other ingredients

Carbomer 940, FD&c Blue # 1 ,Isopropyl alcohol, Propylene Glycol , Purified Water , Sodium Hydroxide .

MADE IN INDIA

Distributed by : JMD ALL STAR IMPEX INC ,Edison,NJ. USA.



ITEM NO # 9917

BLUE ICE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51444-002
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
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51444-002-76	216 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	06/15/2010	

Labeler - JMD All Star Impex Inc (962316662)

Establishment

Name	Address	ID/FEI	Business Operations
Steller Mercantile Pvt.Ltd.		650493005	manufacture

Revised: 5/2010

JMD All Star Impex Inc