BLUE ICE ANALGESIC GEL- menthol gel
Select Brand Distributors

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.

Drug Facts

Active Ingredient

Menthol 2.0%

Uses

- Temporary relief of minor aches and pains in: muscles and joints.

Directions

Directions:

- See important warnings under "When Using This Product".
- Do not apply to children under 2 years of age, unless advised by a physician.
- Adults and children over 2 years of age and older: Apply liberally to painful area and massage until gel is absorbed into skin. Repeat no more than 3-4 times daily.

Warnings

- For external use only.
- Avoid contact with eyes and mucus membranes.

When using this product, do not:

- use with heating pads or heating devices
- use, pour, spill or store near open flame
- use with other creams, sprays or liniments
- apply to damaged skin or wounds
- bandage area tightly

To do so may result in excessive skin irritation or skin burn.

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and consult a physician. If you have sensitive skin consult a physician. If skin irritation develops, discontinue use and seek the advice of a physician before using this product.

Purpose

- Analgesic.

INACTIVE INGREDIENTS

INACTIVE INGREDIENTS: WATER, ISOPROPYL ALCOHOL, CARBOMER, THYMOL, AMMONIUM HYDROXIDE, SODIUM HYDROXIDE, MAGNESIUM SULFATE, FD&C BLUE 1.

Keep out of reach of children

- In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

BLUE ICE ANALGESIC GEL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:15127-452
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.0 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	88.05 g in 100 g
ISOPROPYL ALCOHOL (UNII: ND2M416302)	8.91 g in 100 g
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	0.667 g in 100 g
THYMOL (UNII: 3J50XA376E)	0.2 g in 100 g

AMMONIA (UNII: 5138Q19F1X)	0.06 g in 100 g
SODIUM HYDROXIDE (UNII: 55X04QC32I)	0.1 g in 100 g
MAGNESIUM SULFATE (UNII: DE08037SAB)	0.01 g in 100 g
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	0.003 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15127-452-08	227 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/06/2014	

Labeler - Select Brand Distributors (043562370)

Establishment

Name	Address	ID/FEI	Business Operations
Delon Laboratories (1990) Ltd		243387722	label(15127-452) , manufacture(15127-452) , pack(15127-452)

Revised: 10/2014 Select Brand Distributors