BLUE ICE ANALGESIC- menthol gel
Delon Laboratories (1990) Ltd

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.

Blue Ice Gel

Active ingredient

Menthol 2.0%

Purpose

Topical analgesic

Uses

- for the temporarily relief of minor aches and pains of muscles and joints

Warnings

For external use only

When using this product
- avoid contact with the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if
- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

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

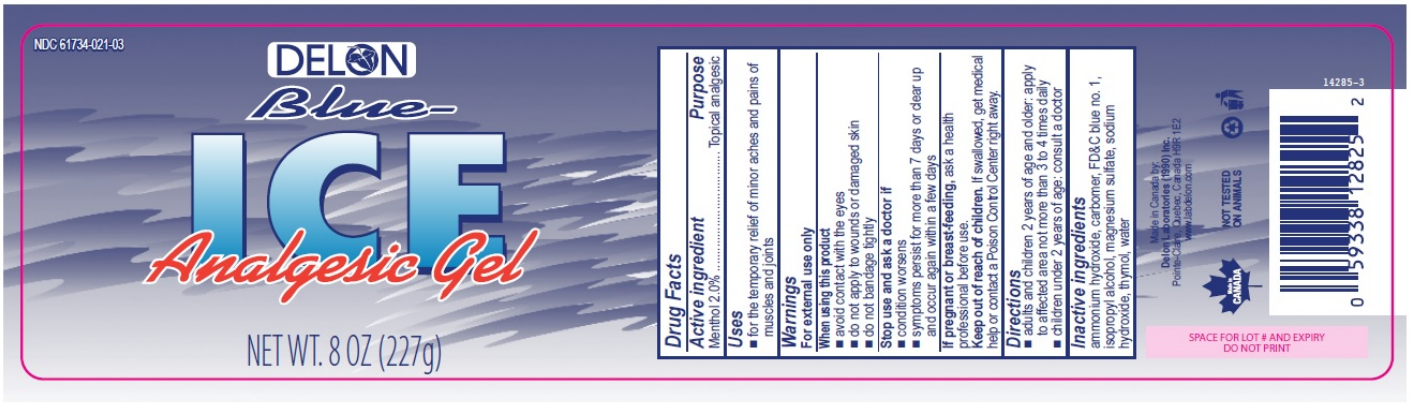
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a doctor

Inactive ingredients

ammonium hydroxide, carbomer, FD&C blue no. 1, isopropyl alcohol, magnesium sulfate, sodium hydroxide, thymol, water

Delon 8oz (227g)



Penetro 227g

BLUE ICE ANALGESIC

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61734-021
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**

THYMOL (UNII: 3J50XA376E)	
AMMONIA (UNII: 5138Q19F1X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T)	
CARBOMER 934 (UNII: Z135WT9208)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61734-021-01	100 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/07/2010	11/06/2017
2	NDC:61734-021-02	113.56 g in 1 CONTAINER; Type 0: Not a Combination Product	05/07/2010	12/04/2014
3	NDC:61734-021-03	227 g in 1 CONTAINER; Type 0: Not a Combination Product	05/07/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/07/2010	

Labeler - Delon Laboratories (1990) Ltd (248364184)

Establishment

Name	Address	ID/FEI	Business Operations
Delon Laboratories (1990) Inc.		243387722	manufacture(61734-021) , pack(61734-021) , label(61734-021)

Revised: 10/2021 Delon Laboratories (1990) Ltd