

CORALITE BLUE ICE- menthol gel

United Exchange Corp.

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

Purpose

Menthol 2%.....Topical analgesic

Uses

- temporarily relieves minor aches and pains of muscles and joints associated with:
- arthritis
- simple backache
- strains
- bruises
- sport injuries
- sprains
- provides cooling penetrating relief

Warnings

For external use only

Do not use

- with other topical pain relievers
- with heating pads or heating devices

When using this product

- do not use in or near the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days
- redness or irritation develops

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

- Clean affected area before applying product
- 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: ask a doctor

Other information

- store in a cool place
- keep lid tightly closed
- do not use, pour, spill or store near heat or open flame

Inactive ingredients

ammonium hydroxide, carbomer 940, cupric sulfate, FD&C blue no. 1, isopropyl alcohol, magnesium sulfate heptahydrate, purified water, sodium hydroxide, thymol

Distributed by:

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Made in China



CORALITE BLUE ICE

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65923-157
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.02 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
CUPRIC SULFATE (UNII: LRX7AJ16DT)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
THYMOL (UNII: 3J50XA376E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65923-157-27	227 g in 1 JAR; Type 0: Not a Combination Product	10/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/05/2016	

Labeler - United Exchange Corp. (840130579)

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