

BLUE ICE TOPICAL ANALGESIC- menthol and camphor gel
FOUR SEASONS TRADING 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.

Blue Ice Topical Analgesic Gel

Active Ingredients

Menthol	1.0%
Camphor	0.5%

Purpose

Topical Analgesic

Uses

For the temporary relief of minor pains and aches of your muscles and joints associated with:

- Sports Injuries
- Sprains
- Arthritis
- Bruises

Warnings

For external use only. Avoid contact with eyes.

Ask a doctor before use if you have cough associated with :

- smoking
- excessive phlegm
- asthma
- emphysema
- persistent or chronic cough

When using this product, do not

- heat
- microwave
- add to hot water or any container where heating water may cause splattering and result in burns
- use in eyes or directly on mucous membranes
- take by mouth or place in nostrils
- apply to wounds or damaged skin
- bandage skin

Do not use with heating devices or pads.

Consult a doctor and discontinue use if condition worsens, persists for more than 1 week or tends to recur.

Keep out of reach of children

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Directions: see important warnings under “When using this product”

adults and children 2 years and over:

- apply to the affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician.

Inactive Ingredients

Aqua, Isopropyl Alcohol, Propylene Glycol, Carbopol, PEG-40 Hydrogenated Castor Oil, Sodium Hydroxide, Disodium EDTA, Benzyl Alcohol, BHT & FD&C Blue No.1

PRINCIPAL DISPLAY PANEL

BLUE ICE TOPICAL ANALGESIC GEL

NET WT. 8 OZ (227g)



BLUE ICE TOPICAL ANALGESIC

menthol and camphor gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69274-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMO POLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69274-004-15	127 g in 1 TUBE		
2	NDC:69274-004-16	170 g in 1 TUBE		
3	NDC:69274-004-13	170 g in 1 BOTTLE, PLASTIC		
4	NDC:69274-004-17	227 g in 1 BOTTLE, PLASTIC		
5	NDC:69274-004-18	300 g in 1 BOTTLE, PLASTIC		
6	NDC:69274-004-19	500 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/25/2014	

Labeler - FOUR SEASONS TRADING INC (169331464)**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(69274-004)