PAIN RELIEVING ANALGESIC- menthol gel
Singhfam Corporation

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.

Analgesic Gel

Active Ingredients

Menthol 2%

Purpose

Topical Analgesic

Uses

For temporary relief of minor aches and muscles pain: simple back aches, sprains and strains common to sports activities, joint pains associated with arthritis.

Directions

Clean skin of all other lotions, creams, ointments, liniments: Apply liberally to affected area and massage until gel is absorbed into skin. Do not apply more than 3 or 4 times within a 24 hour period. No protective cover needed. Do not apply to children under 2 years of age.

Warnings

Use only as directed.

Keep out of reach of children.

For external use only. If swallowed contact a physician or poison control center immediately. Avoid contact with eyes and mucous membranes. Do not apply to open wounds or damaged skin. Make sure skin is clean and free of any creams ointments, sprays or liniments. Do not cover with bandage.

Do not use

with heating pads or heating devices.

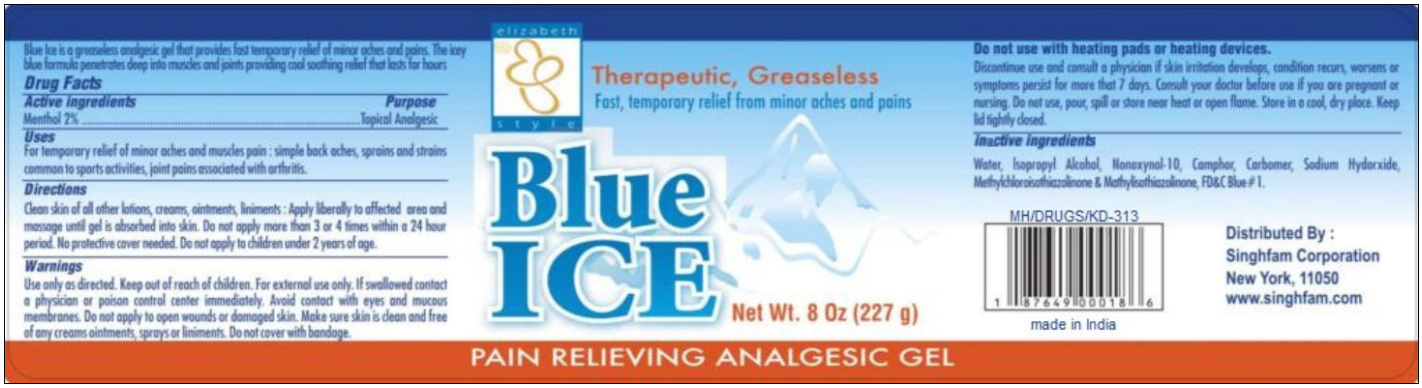
Discontinue use and consult a physician if skin irritation develops, condition recurs, worsens or symptoms persist for more that 7 days. Consult your doctor before use if you are pregnant or nursing. Do not use, pour, spill or store near heat or open flame. Store in a cool, dry place. Keep lid tightly closed.

Inactive Ingredients

Water, Isopropyl Alcohol, Nonoxynol-10, Camphor, Carbomer, Sodium Hydroxide, Methylchloroisothiazolinone & Mathylisothiazolinone, FD&C Blue #1.

PRINCIPAL DISPLAY PANEL
elizabeth style

Therapeutic, Greaseless
Fast, temporary relief from minor aches and pains
Blue Ice
Net Wt. 8 Oz (227 g)
PAIN RELIEVING ANALGESIC GEL



PAIN RELIEVING ANALGESIC

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52920-123
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4.54 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOMER 934 (UNII: Z135WT9208)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
NONOXYNOL-10 (UNII: K7O76887AP)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52920-123-03	227 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/21/2009	

Labeler - Singhfam Corporation (019499958)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd.		916837425	MANUFACTURE(52920-123)

Revised: 1/2012 Singhfam Corporation