ARCTIC ICE PAIN RELIEVING- menthol gel Ningbo Liyuan Daily Chemical Products Co., 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.

Active Ingredient:

Menthol, 2 percentage

Purpose

Topical analgesic

Uses:

Temporarily relieves:

minor muscle aches and pains

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

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:

For the temporary relief of minor muscle aches and pains.

See important warnings under "When using this product"

- not for use on children under 2 years of age
- adults & children 2 years & older: Apply liberally to painful area and massage until gel is absorbed into the skin. Repeat 3 to 4 times daily.

Inactive Ingredients:

Blue 1, Camphor, Carbomer, Isopropyl Alcohol, Methylchoroisothiazolinone, Methylisothiazolinone, Sodium Hydroxide, Water.



ARCTIC ICE PAIN RELIEVING

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76176-251
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		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)			
WATER (UNII: 059QF0KO0R)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
CAMPHOR (NATURAL) (UNII: N20HL7Q941)			

ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER 934 (UNII: Z135WT9208)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:76176-251- 01	198 g in 1 JAR; Type 0: Not a Combination Product	10/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/01/2020	

Labeler - Ningbo Liyuan Daily Chemical Products Co., Ltd. (530766098)

Registrant - Ningbo Liyuan Daily Chemical Products Co., Ltd. (530766098)

Revised: 1/2022 Ningbo Liyuan Daily Chemical Products Co., Ltd.