NUVALU ICE THERAPY MENTHOL 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.

Drug Facts
Active Ingredients

Menthol 1.25 percent

Purpose

Topical Analgesic

USE:

for the temporary relief of minor aches and pains in muscles and joints associated with:

simple backache, strains, sprains, sports injuries, arthritis, bruises

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 eyes
- Do not apply to wounds or damaged skin
- Do not bandage tightly

Stop use and ask 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 Posion 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

Inactive Ingredients:

Water (Aqua), Ethyl Alcohol, Camphor, Carbomer, Disodium EDTA, Methylchloroisothiazolinone, Methylisothiazolinone, Triethanolamine, FD&C Blue No.1

NUVALU ICE THERAPY MENTHOL PAIN RELIEVING

menthol gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76176-222
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

Inactive Ingredients

Ingredient Name	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TRIETHANOLAMINE BENZOATE (UNII: M3EN4GC19W)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
CARBOMER 934 (UNII: Z135WT9208)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76176-222-24	227 g in 1 JAR; Type 0: Not a Combination Product	11/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/01/2018	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Liyuan Daily Chemical Products Co., Ltd.		530766098	manufacture(76176-222)

Revised: 11/2018 Ningbo Liyuan Daily Chemical Products Co., Ltd.