

**ICE COLD ANALGESIC- 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.*

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**Active ingredient**

Menthol 1 percentage

**Purpose**

Topical analgesic

**Uses**

temporarily relieves minor aches and pains of muscles and joints associated with:

- arthritis
- simple backache
- strains
- bruises
- sports 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

skin 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 3-4 times daily.

children under 2 years of age: ask a doctor

## Other information

- store at controlled room temperature 20 to 25 degrees Celsius (68 to 77 Fahrenheit) in a tightly closed container
- do not use, pour, spill or store near heat or open flame

## Inactive ingredients

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

The image shows the packaging for ICE COLD ANALGESIC GEL. The box is blue and white with a mountain graphic. The brand name 'ICE COLD' is prominent in large, bold letters. Below it, 'ANALGESIC GEL' is written in a red banner. The net weight is listed as 'NET WT. 8 OZ (227 g)'. On the right side of the box, there is a vertical strip containing detailed information: 'Drug Facts', 'Active Ingredient' (Menthol 1%), 'Purpose' (Topical analgesic), 'Uses' (temporarily relieves minor aches and pains), 'Warnings' (do not use with other topical pain relievers), 'Directions' (clean affected area before applying), and 'Other Information' (store at controlled room temperature). A barcode is also visible on the right side.

## ICE COLD ANALGESIC

menthol gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 176-066
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
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
WATER (UNII: 059QF0K00R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>CARBOMER 934</b> (UNII: Z135WT9208)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76176-066-01	227 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/01/2020	

**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(76176-066)