# ICE COLD ANALGESIC- menthol gel Volume Distributors, 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.

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#### Active Ingredient Purpose

Menthol 1.0% ..... Topical Analgesic

**Uses** temporarily relieves:

• minor muscle aches and pains

**Except out of reach of children.** Eln case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

DT for your DailyTouch

Ice Cold Analgesic Gel

Gel Frio Antimuscular

#### **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.

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#### **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:

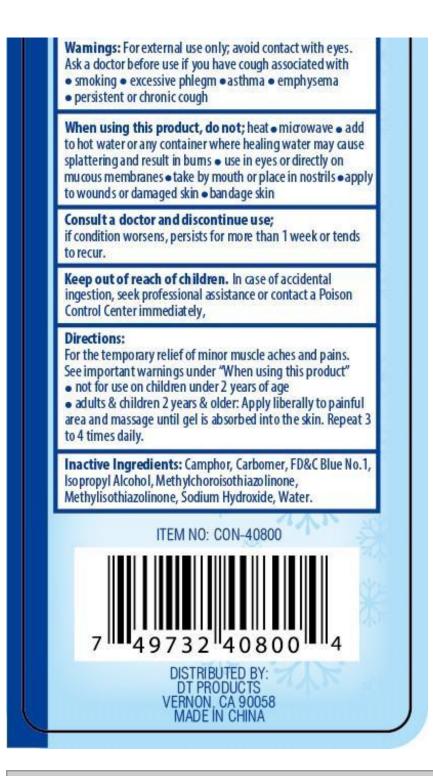
- heat
- microwave
- add to hot water or any container where healing water may cause splattering and result in burns
- use in eyes or directly on mucous membranes
- take my mouth or place in nostrils
- apply to wounds or damaged skin
- bandage skin

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

#### **Inactive Ingredients**

camphor, carbomer, FD&C blue no.1, isopropyl alcohol, methylchloroisothiazolinone, methylisothiazolinone, sodium hydroxide, water.





### ICE COLD ANALGESIC

menthol gel

 Product Information

 Product Type
 HUMAN OTC DRUG
 Item Code (Source)
 NDC:50-23-087

 Route of Administration
 TOPICAL
 V
 V

 Active Ingredient/Active Moievee
 V
 V
 V

 MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)
 MENTHOL
 MENTHOL
 1 g in 100 g

Inactive Ingredient	ts				
	Strength				
CAMPHOR (NATURAL)					
CARBOMER COPOLYM					
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)					
ISOPROPYL ALCOHOI					
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)					
METHYLISOTHIAZOLI					
SO DIUM HYDRO XIDE (					
WATER (UNII: 059QF0K					
Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
<b>1</b> NDC:50523-087-01 22	27 g in 1 PACKAGE; Type 0: Not a Combination Product				
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	l part348	07/10/2015			

## Labeler - Volume Distributors, Inc. (002029544)

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
Volume Distributors, Inc.		002029544	manufacture(50523-087)			

Revised: 7/2015

Volume Distributors, Inc.