# XTRACARE ICE COLD TOPICAL ANALGESIC GEL- menthol gel China Ningbo Shangge Cosmetic Technology Corp

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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# **XtraCare Ice Cold Topical Analgesic Gel**

Active Ingredients: Purpose

Menthol 1.25% ...... Topical Analgesic

**□Uses** 

for the temporary relief of minor aches and pains of muscles and joints.

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

XtraCare® Ice Cold Topical Analgesic Gel

Net Wt 8 oz (227 g)

# □ Warnings

# **IFor 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 eves 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.

#### Directions

- see important warnings under "When using this product"
- adults & children 2 years of age & older: apply to the affected area not more than 3 to 4 times daily.
- children under 2 years of age: consult a physician

#### **Inactive Ingredients:**

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

**Other information:** store at 200 to 25oC (68o to 77oF)

**Questions/Comments?** 1-855-345-5575

DISTRIBUTED BY:
REJOICE INTERNATIONAL INC
NORTHVILLE, MI 48168 USA
MADE IN CHINA





# XTRACARE ICE COLD TOPICAL ANALGESIC GEL

menthol gel

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	3 g in 227 g	

Inactive Ingredients			
Ingredient Name	Strength		
CAMPHOR (NATURAL) (UNII: N20HL7Q941)			
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)			
ALCOHOL (UNII: 3K9958V90M)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
METHYLCHLORO ISO THIAZO LINO NE (UNII: DEL7T5QRPN)			
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
WATER (UNII: 059QF0KO0R)			

Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58503-052-01	227 g in 1 BOTTLE; Type 0: Not a Combination Product	0 1/30 /20 14	
2	NDC:58503-052-02	227 g in 1 TUBE; Type 0: Not a Combination Product	0 1/30 /20 14	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	0 1/30/20 14		

# Labeler - China Ningbo Shangge Cosmetic Technology Corp (529287434)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(58503-052)	

Revised: 8/2018 China Ningbo Shangge Cosmetic Technology Corp