

XTRACARE ICE COLD TOPICAL ANALGESIC GEL- menthol gel
Rejoice International

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

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.

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 20o 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 Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	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)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-052-	227 g in 1 BOTTLE; Type 0: Not a Combination	01/20/2014	

1	01	Product	01/30/2014	
2	NDC:57337-052-02	227 g in 1 TUBE; Type 0: Not a Combination Product	01/30/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/30/2014	

Labeler - Rejoice International (078741245)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(57337-052)

Revised: 10/2023

Rejoice International