

XTRACARE VAPORIZING CHEST RUB- camphor, 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.

XtraCare Vaporizing Chest Rub

☐Active Ingredients

Purpose

Camphor 4.8% Cough Suppressant

Menthol 1.0% Topical Analgesic

☐Uses

- on chest and throat, temporarily relieves cough as may occur with common cold and minor bronchial irritation.
- for the temporary relief of pain associated with minor skin irritation.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

XtraCare® Vaporizing Chest Rub

Cough Suppressant

Net Wt 4 Oz (113 g)

☐Warnings

For external use only; avoid contact with eyes.

Do not use

- by mouth
- in nostrils
- on wounds or damaged skin
- with tight bandages

☐Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma or emphysema

☐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.

☐Stop use and ask a doctor if

- muscle aches and pains persist more than 7 days or come back
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

☐If pregnant or breast-feeding☐, ask a health professional before use.

☐Directions

- ☐see important warnings under "When using this product"
- adults and children 2 years old and older:

- rub a thick layer on chest & throat or rub on sore aching muscles
- cover with a warm, dry cloth if desired
- keep clothing loose about throat chest to help vapors reach the nose/mouth
- repeat up to three times per 24 hours or as directed by doctor
- children under 2 years: do not use

Inactive Ingredients:

cedarleaf oil, nutmeg oil, petrolatum, thymol, turpentine oil

Other Information: store at room temperature

Questions/Comments? 1-855-345-5575

DISTRIBUTED BY:

REJOICE INTERNATIONAL INC

NORTHVILLE, MI 48168 USA

MADE IN CHINA



XTRACARE VAPORIZING CHEST RUB			
camphor, menthol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58503-051
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)		CAMPHOR (NATURAL)	5 g in 113 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	1 g in 113 g
Inactive Ingredients			
Ingredient Name			Strength
CEDAR LEAF OIL (UNII: BJ169U4NLG)			
NUTMEG OIL (UNII: Z1CLM48948)			
PETROLATUM (UNII: 4T6H12BN9U)			
THYMOL (UNII: 3J50XA376E)			

TURPENTINE OIL (UNII: C5H0QJ6V7F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58503-051-01	113 g in 1 BOTTLE; 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 final	part341	01/30/2014	

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

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(58503-051)

Revised: 9/2019

China Ningbo Shangge Cosmetic Technology Corp.