

COLD RUB - camphor eucalyptus oil menthol ointment
JMD All Star Impex 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.

Active Ingredients

Camphor 4.8%

Eucalyptus oil 1.2%

Menthol 2.8%

PURPOSE

cough suppressant/topical analgesic
nasal decongestant/cough suppressant
cough suppressant/topical analgesic

Uses

Temporarily relief for throat and chest

- Cough
- Nasal congestion due to common cold
- Aching muscles
- Minor aches and pains

Warning

For external use only. Avoid contact with eyes.

Do not use

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

Ask a doctor before use if you have

- Asthma
- Excessive phlegm (mucus)
- Emphysema
- Persistent or chronic cough
- Cough associated with smoking

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

Keep out of reach of children. If case of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Directions

- See important warnings under "When using product"
- Children under 2 years of age, ask a doctor before using the product
- Adults and children 2 years of age and older: rub a thick layer chest and throat or sore aching muscles. If desired loosely cover with a soft cloth but keep clothing loose. Repeat up to 3 times daily

Other Information

- Store at room temperature

Other Ingredients

Cedar leaf Oil, Mineral Oil, Nutmeg Oil, Petrolatum, Spirits of Turpentine, Thymol

Package Label



Drug Facts

Active Ingredients

	Purpose
Camphor 4.8%.....	cough suppressant/ topical analgesic
Eucalyptus oil 1.2 %.....	nasal decongestant /cough suppressant
Menthol 2.8 %.....	cough suppressant/topical analgesic

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 ■ On wounds or damaged skin ■ with light bandages

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 ■ Emphysema ■ Persistent or chronic cough ■ Cough associated with smoking

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

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a poison Control Center immediately

Direction

- See important warnings under " When using product"
- Children under 2 years of age, ask a doctor before using the product
- Adults and children 2 years and older: rub liberally on chest and throat or sore aching muscles. If desired cover with a dry soft cloth but keep clothing loose. Repeat up to 3 times daily.

Other Information ■ Store at room temperature

Other Ingredients

Cedar-leaf Oil,Mineral Oil, Nutmeg Oil,Petrolatum , Spirits of Turpentine, Thymol

MADE IN INDIA

Distributed by : JMD ALL STAR IMPEX INC ,Edison,NJ. USA.



ITEM NO #

COLD RUB

camphor eucalyptus oil menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51444-001
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Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	4.8 g in 100 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.2 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.8 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CEDAR LEAF OIL (UNII: BJ169U4NLG)	
NUTMEG (UNII: AEE24M3MQ9)	
PETROLATUM (UNII: 4T6H12BN9U)	
THYMOL (UNII: 3J50XA376E)	
TURPENTINE (UNII: XJ6RUH0O4G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51444-001-38	108 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2010	

Labeler - JMD All Star Impex Inc. (962316662)

Establishment

Name	Address	ID/FEI	Business Operations
Steller Mercantile Pvt.Ltd.		650493005	manufacture

Revised: 5/2010

JMD All Star Impex Inc.