

MEDICATED CHEST RUB- camphor, menthol, eucalyptus oil cream

Family Dollar Services 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.

MEDICATED CHEST RUB

Active ingredients

Camphor	4.8%
Menthol	2.6%
Eucalyptus oil	1.2%

Purpose

Cough suppressant /topical analgesic

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Cough suppressant

Uses

Temporarily relieves throat and chest

- cough
- nasal congestion due to common cold
- aching muscles
- minor aches and pains

Warnings

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

When using this product do not heat

- microwave
- use near open flame
- 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/pain persist more than more than 7 days or come back
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

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.

Directions

- see important warnings under "When using this product"
- children under 2 years of age, ask a doctor before using the product
- adults and children 2 years and older, rub a thick layer on chest and throat or rub on 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

Inactive ingredients

cedar leaf oil, nutmeg oil, paraffin, petrolatum, thymol, turpentine oil

PRINCIPAL DISPLAY PANEL

MEDICATED CHEST RUB

camphor, menthol, eucalyptus oil cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.8 g in 100 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 g in 100 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CEDAR LEAF OIL (UNII: BJ169U4NLG)	
NUTMEG OIL (UNII: Z1CLM48948)	
PARAFFIN (UNII: I9O0E3H2ZE)	

PETROLATUM (UNII: 4T6H12BN9U)

THYMOL (UNII: 3J50XA376E)

TURPENTINE OIL (UNII: C5H0QJ6V7F)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-102-01	113 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/19/2011	

Labeler - Family Dollar Services Inc (024472631)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(55319-102)

Revised: 11/2013

Family Dollar Services Inc