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 supressan

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

Ask a doctor before use if you have

- asthma
- excessive phlem (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 profesional before use

Keep out reach of children.

In case of accidental ingestion get medical help or contact a Poison Control Center right away.

Directions

- see important warnings when using this product
- children under 2 years of age, ask a doctor before using this product
- adults and children 2 years older, rub a thick layer on chest and 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, patrolatum, thymol, turpentine oil



Medicated chest rub

4 oz (113 g)



MEDICATED CHEST RUB

camphor, menthol, eucalyptus oil cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-100
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Route of Administration TOPICAL

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

Inactive Ingredients			
Ingredient Name	Strength		
CEDAR LEAF OIL (UNII: BJ169U4NLG)			
NUTMEG OIL (UNII: Z1CLM48948)			
PARAFFIN (UNII: 1900E3H2ZE)			
PETROLATUM (UNII: 4T6H12BN9U)			
THYMOL (UNII: 3J50 XA376E)			
TURPENTINE (UNII: XJ6RUH0O4G)			

F	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-100-01	113 g in 1 JAR		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part348	07/19/2011		

Labeler - Family Dollar Services Inc (024472631)

Registrant - Blue Cross Laboratories (008298879)

Establishment				
Name	Address	ID/FEI	Business Operations	
Blue Cross Laboratories		008298879	manufacture(55319-100)	

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(55319-100)

Revised: 11/2012 Family Dollar Services Inc