VAPORIZING CHEST RUB- menthol and camphor and eucalyptus oil gel Quality Care Distributors LLC

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.

Vaporizing Chest Rub

Drug Facts

Active Ingredients

Camphor 4.7% Menthol 1.0% Eucalyptus Oil 1.0%

Purpose

Cough suppressant, nasal decongestant & topical analgesic

Use:

Temporarily relives symptoms associated with the common cold:

- cough
- nasal congestion
- chest congestion

Temporarily relieves minor aches and pains of muscles.

Directions:

See important warning under

"Do not use this product"

- Children under 2 years of age, ask a doctor.
- Adults and children 2 years of age or older: Rub a thick layer on chest and throat. If desired, loosely cover with a soft dry cloth but keep clothing loose.
- Repeat up to 3 times daily, or as directed by a doctor.

Warnings:

For external use only: Avoid contact with eyes

Ask a doctor before use if you have:

Chronic cough that lasts or as occurs with smoking, asthma or emphysema. Cough with excessive phlegm (mucus).

Do not use this product;

Near an open flame. By adding water. By mouth. In a microwave oven. On wounds or damaged skin. With tight bandages. In nostrils. Added to hot water or any container where you are heating water. May

cause splattering and result in burns.

Stop use and ask a doctor if:

Muscles aches and pains persist for more than 7 days or come back. Cough lasts more that 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, consult a physician before use

Keep out of reach of children.

If swallowed, get medical helps or contact a Poison Control Center immediately

Inactive Ingredients:

Petrolatum, Nutmeg Oil, Turpentine Oil, Cedar Leaf Oil, Thymol, Paraffin.

Principal Display Panel

NEW! FamilyCare Chest Rub VAPORIZING ACTION Nasal Decongestant Cough Suppressant NET WT. 4 OZ (113g)





VAPORIZING CHEST RUB

menthol and camphor and eucalyptus oil gel

Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source)		NDC:52271-158	
Route of Administration	TOPICAL				
Active Ingredient/Active Moi	ety				
Ing	gredient Name		Basis of Str	rength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD UNII:5TJD82A1ET)	82A1ET) (CAMPHOR (SYNTHET	IC) -	CAMPHOR (SYNTHETIC)		5.31 g in 113 g
EUCALYPTUS OIL (UNII: 2R04ONI66	2) (EUCALYPTUS OIL - UNII:2R0	40NI662)	EUCALYPTUS	OIL	1.13 g in 113 g

EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662) MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)

Inactive Ingredients			
II	igredient Name	Strength	
PETROLATUM (UNII: 4T6 H12BN9U)			
PARAFFIN (UNII: 1900E3H2ZE)			
NUTMEG OIL (UNII: Z1CLM48948)			
TURPENTINE (UNII: XJ6 RUH0 O4G)			

MENTHOL

1.13 g in 113 g

THYMOL (UNII: 3J50XA376	5E)				
CEDAR LEAF OIL (UNII: B.	J169U4NLG)				
Packaging					
# Item Code	Package Description	Marketing	Start Date	Ma	rketing End Date
1 NDC:52271-158-01	113 g in 1 JAR				
Marketing Inform	nation				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date
OTC MONOGRAPH FINAL	part341		09/21/2009		

Labeler - Quality Care Distributors LLC (961937112)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd.		916837425	MANUFACTURE

Revised: 7/2010

Quality Care Distributors LLC