

VAPORIZING CHEST RUB- menthol and camphor and eucalyptus oil gel
Singhnam Corporation

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

Active Ingredients

Menthol 2.0%

Camphor 4.7%

Eucalyptus Oil 1.0%

Purpose

Decongestant

USES:

- On chest and throat for temporary relief of nasal congestion and cough due to common cold.
- On muscles and joints for temporary relief of minor aches and pains.

Warnings:

- **For external use only**
- **Avoid contact with eyes**

Keep out of reach of children

if swallowed, seek medical attention or contact a poison control center immediately.

If pregnant or breast-feeding,

consult your doctor before use.

Do not use

near mouth, in nose, with tight bandages, on wounds or damaged skin.

Consult a doctor before use

if you have a cough with too much phlegm/mucus; persistent or chronic cough associated with asthma, emphysema or smoking.

when using this product,

do not heat, microwave, add to hot water or any container in which water is heating as splattering may occur resulting in burns.

Discontinue use and consult a doctor

if you experience:

- recurring or persistent Cough that lasts for more than 7 days or occurs with fever, rash or headache.
- recurring or persistent muscle or joint aches and pains.

These symptoms may be a sign of a serious condition.

Directions:

- For adults and children 2 years of age and over.
- Apply a thick layer on throat and chest or rub on sore muscles and joints.
- Cover loosely with a warm dry cloth if desired.
- Keep clothing loose around throat and chest to allow vapors to reach the nose and mouth.
- Apply no more than 3 times in a 24 hour period or as directed by doctor.

Other information:

Store at room temperature away from heat or flame.

Inactive Ingredients:

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

PRINCIPAL DISPLAY PANEL

elizabeth style

Vaporizing Chest Rub

Nasal Decongestant and Cough Suppressant

NET WT 4 OZ (113 G)

VAPORIZING CHEST RUB

menthol and camphor and eucalyptus oil gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52920-124
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.7 g in 113 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.1 g in 113 g

EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.1 g in 113 g
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Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
NUTMEG OIL (UNII: Z1CLM48948)	
TURPENTINE OIL (UNII: C5H0QJ6V7F)	
THYMOL (UNII: 3J50XA376E)	
CEDAR LEAF OIL (UNII: BJ169U4NLG)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52920-124-04	113 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/10/2010	

Labeler - Singhfam Corporation (019499958)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd.		916837425	MANUFACTURE(52920-124)

Revised: 1/2012

Singhfam Corporation