

VAPORIZING CHEST RUB COUGH SUPPRESSANT- camphor (synthetic), eucalyptus oil, and menthol ointment

Filo America

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	Purpose
Camphor 4.7%	Cough suppressant/topical analgesic
Eucalyptus oil 1%	Cough suppressant
Menthol, natural 1%	Cough suppressant / topical analgesic

Use

when applied to chest and throat

- temporarily relieves cough due to minor throat and bronchial irritation associated with a cold

when applied to muscles and joints

- temporarily relieves minor aches and pains of muscles and joints

Warnings

For external use only; avoid contact with eyes.

Ask a doctor before use if you have

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

When using this product

- do not heat
- do not microwave
- do not add to hot water or any container where heating water. May cause splattering and result in burns.
- do not take by mouth or place in nostrils

Stop use and ask a doctor if

- cough persists for more than 1 week, tends to recur or is accompanied by fever, rash, or persistent cough may be a sign of a serious condition.
- muscle aches and pains worsen, persist for more than 7 days, or clear up occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- see important warnings under "When using this product"
- adults and children 2 year and over.

for cough suppression

- rub a thick layer on the throat and chest
- cover with a warm, dry cloth if desired
- keep clothing loose about throat and chest to help vapors reach the nose and mouth
- use up to 3 times daily, or as directed by a doctor

for muscle/joint minor aches and pains apply

- to affected area not more than 3-4 times daily
- children under 2 years : ask a doctor

other information

- store at room temperature

if pregnant or breast feeding

- ask a health professional before use

Inactive ingredients

Cedar leaf oil, methylparaben, Nutmeg oil, petrolatum, Turpentine oil, Thymol, propylparaben

PRINCIPAL DISPLAY PANEL - 100g Jar Label**VAPORIZING
CHEST RUB**

4 oz (113g)



Drug facts

<i>Active ingredients</i>	<i>Purpose</i>
Camphor (synthetic) 4.7%.....	Cough suppressant & tropical analgesic
Eucalyptus oil 1%	Cough suppressant
Menthol 1%	Cough suppressant & tropical analgesic

Uses • when applied to chest and throat, temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold
 • when applied to muscles and joints, temporarily relieves minor aches and pains of muscles and joints.

Warnings For external use only; avoid contact with eyes.

Do not use • by mouth • in nostrils • on wounds or damaged skin • with tight bandages.

Ask a doctor before use if you have
 • cough that occurs with too much phlegm (mucus)
 • persistent or chronic cough such as occurs with smoking, asthma or emphysema.

When using this product, do not
 • heat • microwave • 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 and pains worsen or persist for more than 7 days or clear up and occur again

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within few days

- cough persists for more than 1 week, tends to recur or is accompanied by fever, rash or persistent cough may be a sign of a serious condition.

If pregnant or breast feeding

ask a health professional before use.

Keep out of reach of children

if swallowed, get medical help or contact a Poison Control Center right away.

Directions

• **see important warnings under "When using this product"**

- adults and children 2 years and over:
 - for cough suppression
 - rub a thick layer on throat & chest
 - cover with a warm, dry cloth if desired
 - keep clothing loose about throat and chest to help vapors reach the nose and mouth
 - use up to three times daily or as directed by doctor
- for muscle / joint minor aches and pains apply to affected area not more than 3 to 4 times daily
- children under 2 years: do not use.

Other information

- store at room temperature.

Inactive ingredients:

cedar leaf oil, methylparaben, nutmeg oil, petrolatum, propylparaben, thymol, turpentine oil.

Distributed by:

Filo America
P.O. Box 23592
Los Angeles, CA 90023
Developed in USA, produced in PRC

Questions or Concerns?

1.866.460.0322



VAPORIZING CHEST RUB COUGH SUPPRESSANT

camphor (synthetic), eucalyptus oil, and menthol ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50438-502
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 100 g
Eucalyptus Oil (UNII: 2R04ONI662) (Eucalyptus Oil - UNII:2R04ONI662)	Eucalyptus Oil	1 g in 100 g
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Nutmeg Oil (UNII: Z1CLM48948)	0.6 g in 100 g
TURPENTINE OIL (UNII: C5H0QJ6V7F)	
Petrolatum (UNII: 4T6H12BN9U)	
propylparaben (UNII: Z8IX2SC1OH)	
THYMOL (UNII: 3J50XA376E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50438-502-01	113 g in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/05/2015	

Labeler - Filo America (943873703)

Registrant - Ningbo Pulisi Daily Chemical Products Co., Ltd. (529047265)

Establishment

Name	Address	ID/FEI	Business Operations
Ningbo Pulisi Daily Chemical Products Co., Ltd.		529047265	manufacture(50438-502)