

CHEST RUB VAPORIZING- menthol and camphor and eucalyptus oil gel
North & South Wholesalers 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.

Chest Rub Vaporizing

Active Ingredients

Camphor 4.7%

Menthol 1.0%

Eucalyptus Oil 1.0%

Purpose

Decongestant

Uses

- on chest and throat, helps temporarily relieve cough due to common cold
- on joints and muscles, temporary relieves minor aches and pain

Warnings

For external use only, avoid contact with eyes.

Do not use

- by mouth
- in nostrils
- with tight bandages
- on wounds or damaged skin

Ask doctor before use if you have,

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

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:

- cough lasts more than 7 days, comes back, or fever, rash or persistent headache. These could be sign of a serious conditions
- muscle aches and pain persist more than 7 days

Keep out of the reach of children

If ingested get medical help or contact a Poison control center immediately

Directions:

adults and children 2 years and over:

- rub a thick layer on chest and throat or rub on sore aching muscles
- keep clothing loose around chest/throat to help vapors reach the nose/mouth
- repeat up to 3 times per 24 hours or as directed by doctor

do not use on children under 2 years unless directed by doctor

Inactive Ingredients

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

PRINCIPAL DISPLAY PANEL

CHEST RUB VAPORIZING GEL

NASAL DECONGESTANT

COUGH SUPPRESSANT

NET WT. 4 OZ (113g)



CHEST RUB VAPORIZING

menthol and camphor and eucalyptus oil gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:7020 1-004
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
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1 g in 100 g

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70201-004-09	113 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/03/2015	

Labeler - North & South Wholesalers LLC (004948495)**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(70201-004)

Revised: 11/2015

North & South Wholesalers LLC