NUVALU VAPORIZING CHEST RUB- camphor, eucalyptus oil, menthol gel Ningbo Liyuan Daily Chemical Products Co., Ltd.

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.

Active Ingredients

Camphor, 4.7 percent
Eucalyptus Oil, 1 percent
Menthol, 1 percent

Purpose

Cough Suppressant and Topical Analgesic Cough Suppressant Cough Suppressant and Topical Analgesic

USES

on chest and throat, to temporarily relieve cough use on aching muscles to temporarily relieve minor aches

WARNINGS:

For external use only; Do not take by mouth or place in nostrils. Avoid excessive heat. Never expose this product to flame or place in any container in which you are heating water. Never place in microwave oven.

Consult a doctor and discontinue use;

If cough persists for more than 1 week, tends to recur or is accompanied by fever, rash, or persistant headache.

Keep out of reach of children.

In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

DIRECTIONS:

Adults and children over 2 years of age; Rub a thick layer on chest and throat to provide temporary relief from nasal congestion and coughing due to colds. If desired, cover with dry, warm cloth, but keep clothing loose to let the vapors rise to nose and mouth. Repeat up to three times daily, especially at bed time, or as directed by a doctor. Children under two years of age, consult a doctor.

Inactive ingredients:

petrolatum, mineral oil, nutmeg, spirits of turpentine, cedarleaf oil, thymol.



NUVALU VAPORIZING CHEST RUB

camphor, eucalyptus oil, menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76176-221
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)			
TURPENTINE (UNII: XJ6RUH0O4G)			
CEDAR LEAF OIL (UNII: BJ169U4NLG)			
THYMOL (UNII: 3J50 XA376E)			
MINERAL OIL (UNII: T5L8T28FGP)			
PETROLATUM (UNII: 4T6H12BN9U)			

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:76176-221-24	113 g in 1 JAR; Type 0: Not a Combination Product	11/0 1/20 18	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	11/0 1/20 18		

Labeler - Ningbo Liyuan Daily Chemical Products Co., Ltd. (530766098)

Registrant - Ningbo Liyuan Daily Chemical Products Co., Ltd. (530766098)

Establishment					
Name	Address	ID/FEI	Business Operations		
Ningbo Liyuan Daily Chemical Products Co., Ltd.		530766098	manufacture (76 176 - 221)		

Revised: 11/2018 Ningbo Liyuan Daily Chemical Products Co., Ltd.