PHARMACYS PRESCRIPTION VAPOR RUB- 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

Menthol 1 percent
Camphor 4.7 percent
Eucalyptus Oil 1 percent

Purpose

Decongestant

USE:

To temporarily relieve nasal congestion, chest congestion and cough due to the common cold. Temporarily relieves minor aches and pains.

WARNING:

For external use only. Not for internal use. Avoid contact with eyes. Do not put in mouth, nostrils or on wounds or damaged skin.

If pregnant or breast feeding,

consult a physician before use.

Do not use near open flame, in a microwave oven or in a container in which water is being heated except when adding to cold water in a hot steam vaporizer.

Consult a physician before use.

If you have asthma, emphysema, persistent or chronic cough, cough associated with smoking or excessive mucus. If muscle aches persist for more than 7 days or comes back or if cough lasts more than 7 days, come back or occurs with fever, rash or a persistent headache.

Keep out of reach of children.

If ingested, seek medical help or contact a Posion Control Center right away.

Directions:

Adults and children 2 years of age and older rub a thick layer on chest and throat for temporary relief from nasal congestion and coughing due to colds or rub on sore, aching muscles. If desired, loosely cover with a soft dry cloth but keep clothing loose. Repeat up to three times daily, especially at bedtime. Children under 2 years of age, consult your physician.

Inactive Ingredients:

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



PHARMACYS PRESCRIPTION VAPOR RUB

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76176-112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
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	
CAMPHOR (NATURAL) (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941)	CAMPHOR (NATURAL)	4.7 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
PETROLATUM (UNII: 4T6H12BN9U)			
MINERAL O IL (UNII: T5L8T28FGP)			
NUTMEG OIL (UNII: Z1CLM48948)			
TURPENTINE O IL (UNII: C5H0 QJ6 V7F)			
THYMOL (UNII: 3J50 XA376E)			
CEDAR LEAF OIL (UNII: BJ169U4NLG)			

	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:76176-112-01	110 g in 1 JAR; Type 0: Not a Combination Product	08/01/2018	

	Marketing Infor	mation		
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part341	08/01/2018

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 - 112)

Revised: 8/2018

NINGBO LIYUAN DAILY CHEMICAL PRODUCTS CO., LTD.