

VAPOUR RUB- camphor, eucalyptus, menthol ointment
OPMX 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.

VAPOUR RUB

Active Ingredients

CAMPHOR 4.8%

EUCALYPTUS 1.2%

MENTHOL 2.6%

Purpose

COUGH SUPPRESSANT & TOPICAL ANALGESIC

COUGH SUPPRESSANT

COUGH SUPPRESSANT & TOPICAL ANALGESIC

Uses

- ON CHEST & 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)
- PERSISTANT 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 WITHIN A 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 BRAST-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 A 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

CEDARLEAF OIL, NUTMEG OIL, PETROLATUM, SPIRITS OF TURPENTINE, THYMOL

45.0 mm

45.0 mm

45.0 mm

45.0 mm

63.0 mm

63.0 mm

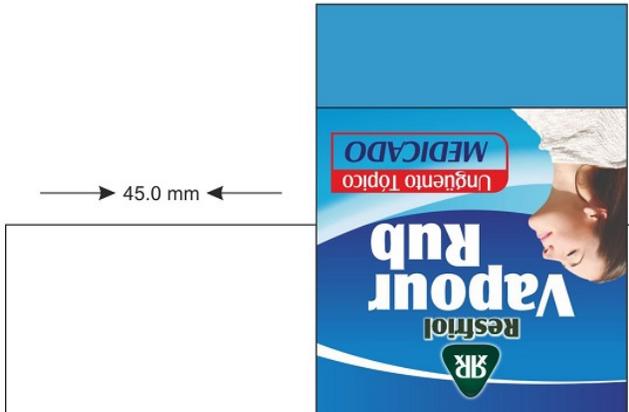
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Failure to follow these warnings could result in serious consequences

Drug Facts

Active Ingredients	Purpose
Camphor 4.8%.....	Cough suppressant & topical analgesic
Eucalyptus Oil 1.2%.....	Cough suppressant
Menthol 2.6%.....	Cough suppressant & topical analgesic

Uses

- on chest & 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

Warning

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 within a 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.



Drug Facts (continued)

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
 cedarwood oil, nutmeg oil, petrolatum, spirits of turpentine, thymol.

Made for: **RRX** San Diego, CA
 Exclusively distributed by: **OPMX** San Diego, CA 92154
 Phone: 619-400-5832
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VAPOUR RUB

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69729-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.8 g in 100 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.2 g in 100 g

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 g in 100 g
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Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69729-101-11	1 in 1 BOX	07/16/2018	
1		100 g in 1 JAR; Type 0: Not a Combination Product		
2	NDC:69729-101-12	1 in 1 BOX	07/16/2018	
2		50 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	07/16/2018	

Labeler - OPMX LLC (029918743)

Revised: 7/2018

OPMX LLC