

VAPOUR RUB- vapor rub ointment
PROSANA DISTRIBUCIONES, S.A. DE C.V.

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 100g

Active Ingredients Purpose

Camphor 4.8 % Cough Suppressant & Topical Analgesic

Eucalyptus Oil 1.2% Cough Suppressant

Menthol 2.6% Cough Suppressant and Topical Analgesic

Uses

-on 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

Store

Other Information-Store at room temperature

Inactive ingredients

Inactive ingredients

cedarleaf oil, nutmeg oil, spirits of turpentine, thymol

Directions-See important warnings under "When Using This Product"

Directions-See important warnings under "When Using This Product"

For External use only

For external use only; avoid contact with eyes

Do not use

-by mouth

-in nostrils

-on wounds

or damaged skin

-with light bandages

Ask a Doctor

Ask a doctor before use if you have

-cough that occurs with too much phlegm

-persistant or chronic cough, such as occurs with smoking, asthma or emphysema

When using this product

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**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 after 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

If pregnant or breastfeeding ask a health professional before use

Keep out

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

Directions

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 and chest

-cover with a warm cloth if desired

-keep clothing loose around throat and chest to help vapors reach the nose and mucus

-use up to three times a day or as directed by a doctor

-for muscle/joint aches and pains apply to affected area no more than 3 to 4 times daily

-children under 2 years do not use

If pregnant

If pregnant or breast feeding, ask a health professional before use

Children

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

Warning

Failure to follow these warnings could result in serious consequences

For external use only, avoid contact with eyes

Do not use-by mouth-in nostrils-on wounds of 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 after 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

Principal display 100 g

RESFRIOL

VAPOUR RUB

TOPICAL OINTMENT -MEDICATED

-Nasal Congestion

-Cough Suppressant

NET WT. 3.53 OZ (100g)



▲ Nasal Congestion
▲ Cough Suppressant
NET WT 3.53 OZ (100g)

Failure to follow these warnings could result in serious consequences.

Drug Facts
Active Ingredients
 Camphor 4.8%, Cough suppressant & topical analgesic Eucalyptus Oil 1.2%, Cough suppressant Menthol 2.8%, Cough suppressant & topical analgesic
Uses
 • on chest & throat; temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold and sore throat; 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 mouth • on wounds or damaged skin • with tight bandages
 • if you have
 • a cough that occurs with too much phlegm (mucus)
 • persistent or chronic coughs such as occurs with smoking, asthma or emphysema
When using this product, do not
 • use it for any condition where heating water. They cause splintering and result in burns.
Stop use and ask a doctor if
 • numbness occurs and persists for more than 7 days or clear up and occur again within a few days
 • cough persists for more than 1 week, vents to react, may be a sign of a serious condition.



▲ Congestión Nasal
▲ Supresor de la Tos
CONT NET 3.53 OZ (100g)

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
 • for cough suppressant, press and over;
 • 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 throat
 • do not use on children under 2 years old
 • 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, rubbing oil, petroleum, spirits of turpentine, thymol
 Made in Mexico
 Exclusively distributed by:
 OPNMX
 San Diego, CA 92154
 Phone 619-400-5432
 QR code and social media icons (Facebook, Twitter, YouTube, Instagram) are also present.

Lot:
Exp:
0 91965 03096 6

VAPOUR RUB vapor rub ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69728-0030

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.2 g in 100 g	
	CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.8 g in 100 g	
	MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	THYMOL (UNII: 3J50XA376E)	1.2 g in 100 g		
	PETROLATUM (UNII: 4T6H12BN9U)	87.3 g in 100 g		
	CEDAR LEAF OIL (UNII: BJ169U4NLG)	1.2 g in 100 g		
	NUTMEG OIL (UNII: Z1CLM48948)	1.2 g in 100 g		
	TURPENTINE OIL (UNII: C5H0QJ6V7F)	0.5 g in 100 g		
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69728-0030-2	1 in 1 BOX	04/05/2017	
1	NDC:69728-0030-1	100 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	04/05/2017		

Labeler - PROSANA DISTRIBUCIONES, S.A. DE C.V. (816197867)

Registrant - PROSANA DISTRIBUCIONES, S.A. DE C.V. (816197867)

Establishment

Name	Address	ID/FEI	Business Operations
PROSANA DISTRIBUCIONES, S.A. DE C.V.		816197867	manufacture(69728-0030)

Revised: 5/2017

PROSANA DISTRIBUCIONES, S.A. DE C.V.