

**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.*

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**VAPOUR RUB 50g**

**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**

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**cedarleaf oil, nutmeg oil, spirits of turpentine, thymol**

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

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**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 PANEL**

**RESFRIOL VAPOUR RUB**

Topical Ointment

MEDICADO/ MEDICADO

Nasal Congestion

-Cough Suppressant

NET WT 1.76 OZ (50g)



<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69728-0020
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	0.6 g in 50 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2.4 g in 50 g
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.3 g in 50 g

### Inactive Ingredients

Ingredient Name	Strength
THYMOL (UNII: 3J50XA376E)	0.6 g in 50 g
PETROLATUM (UNII: 4T6H12BN9U)	43.65 g in 50 g
CEDAR LEAF OIL (UNII: BJ169U4NLG)	0.6 g in 50 g
NUTMEG OIL (UNII: Z1CLM48948)	0.6 g in 50 g
TURPENTINE OIL (UNII: C5H0QJ6V7F)	0.25 g in 50 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69728-0020-2	1 in 1 BOX	04/05/2017	
1	NDC:69728-0020-1	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	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(69728-0020)

Revised: 4/2017

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