# AVEDANA MEDICATED CHEST RUB- camphor eucalyptus menthol ointment Unipack 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.

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#### **AVEDANA ® MEDICATED CHEST RUB**

#### **Active Ingredients**

Ingredients Purpose

Camphor 4.8% cough suppressant/topical analgesic

Eucalyptus Oil 1.2% cough suppressant

Menthol 2.6% cough supressant/topical analgesic

#### Uses

Uses - On chest and throat, temporarily relieves cough due to common cold. On the muscles and joints, temporarily relieves minor aches and pains.

#### Warnings

Warnings

For external use only. Avoid contact with eyes.

#### Do Not Use

Do not use - by mouth - in nostrils - on wounds or damaged skin - with tight bandages

## Ask a doctor before use if you have

asthma - excessive phlegm (mucus) - emphysema - persistent or chronic cough - cough associated with smoking

## If pregnant or breast-feeding

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

### Keep out of reach of children

In case of accidental ingestion, get medical help or contact Poison Control Center immediately.

#### **Directions**

- children under 2 years of age, ask a doctor before using the product - adults and children 2 years and older: rub a thick layer on throat and chest or rub on sore aching muscles. If desired cover with a dry soft cloth, but keep clothing loose. Repeat up to 3 times a day.

#### Other information

store at room temperature

### **Other Ingredients**

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

### **Purpose**

cough suppressant / topical analgesic, cough suppressant

#### **Product Label**



## AVEDANA MEDICATED CHEST RUB

camphor eucalyptus menthol ointment

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43749-110	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.8 g in 100 g	
EUCALYPTUS OIL (UNII: 2R040NI662) (EUCALYPTUS OIL - UNII:2R040NI662)	EUCALYPTUS OIL	1.2 g in 100 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
PETROLATUM (UNII: 4T6H12BN9U)	91.05 g in 100 g			
NUTMEG OIL (UNII: Z1CLM48948)	0.15 g in 100 g			
TURPENTINE (UNII: XJ6RUH0O4G)	0.05 g in 100 g			
CEDAR LEAF OIL (UNII: BJ169U4NLG)	0.05 g in 100 g			
MINERAL OIL (UNII: T5L8T28FGP)	0.05 g in 100 g			
THYMOL (UNII: 3J50XA376E)	0.05 g in 100 g			

ı	Packaging				
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
	1	NDC:43749-110- 04	113 g in 1 JAR; Type 0: Not a Combination Product	09/03/2014	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	09/03/2014		

## Labeler - Unipack LLC (009248480)

## Registrant - Unipack LLC (009248480)

Establishment				
Name	Address	ID/FEI	Business Operations	
Unipack LLC		009248480	manufacture(43749-110)	

Revised: 1/2023 Unipack LLC