### VAPORIZING CHEST RUB- menthol and camphor and eucalyptus oil gel Universal Distribution Center 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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### Vaporising Chest Rub

### **Active Ingredients**

Camphor 4.7%

Menthol 1.25%

Eucalyptus Oil 1.2%

### **Purpose**

Decongestant

#### Uses

- on chest and throat, helps temporarily relive cough due to common cold.
- on joints and muscles, temporarily relives minor aches and pains.

### **Warnings**

### For external use only; avoid contact with eyes.

#### Do not use

- by mouth
- in nostrils
- with tight bandages
- on wounds or damaged skin

## Ask doctor before use if you have,

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma, emphysema, or smoking

# When using this product, do not

- heat
- microwave
- add to hot water or any container where heating water. May cause splattering and results in burns

### Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash or persistent headache. These could be signs of a serious conditions
- muscle aches or pain persist more than 7 days or come back

# Keep out of the reach of children

If ingested get medical help or contact a Poison control center immediately

#### **Directions**

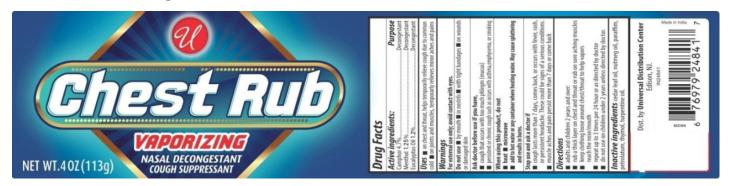
- adults and children 2 years and over
- rub a thick layer on chest and throat or rub on sore aching muscles
- keep clothing loose around chest/throat to help vapors reach the nose/mouth
- repeat up to 3 times per 24 hours or as directed by doctor
- do not use on children under 2 years unless directed by doctor

## **Inactive ingredients**

cedar leaf oil, nutmeg oil, paraffin, petrolatum, thymol, turpentine oil

#### PRINCIPAL DISPLAY PANEL

VAPORISING CHEST RUB NASAL DECONGESTANT AND COUGH SUPPRESSANT NET WT.4 OZ (113g)



### **VAPORIZING CHEST RUB**

menthol and camphor and eucalyptus oil gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52000-039	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.7 g in 100 g	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1.25 g in 100 g	
EUCALYPTUS OIL (UNII: 2R040NI662) (EUCALYPTUS OIL - UNII:2R040NI662)	EUCALYPTUS OIL	1.2 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
CEDAR LEAF OIL (UNII: BJ169U4NLG)				
NUTMEG OIL (UNII: Z1CLM48948)				
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				

THYMOL (UNII: 3J50XA376E)	
TURPENTINE OIL (UNII: C5H0QJ6V7F)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000- 039-08	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2018	
2	NDC:52000- 039-09	56.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2018	
3	NDC:52000- 039-10	100 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2018	
4	NDC:52000- 039-11	113 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2018	
5	NDC:52000- 039-12	150 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2018	
6	NDC:52000- 039-13	170 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2018	
7	NDC:52000- 039-14	226 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/14/2018	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	05/14/2018		

# Labeler - Universal Distribution Center LLC (019180459)

# Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52000-039)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-039)	

Revised: 2/2022 Universal Distribution Center LLC