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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vapourising chest rub

Active Ingredients

Camphor 4.7%

Menthol 1.0%

Eucalyptus Oil 1.0%

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

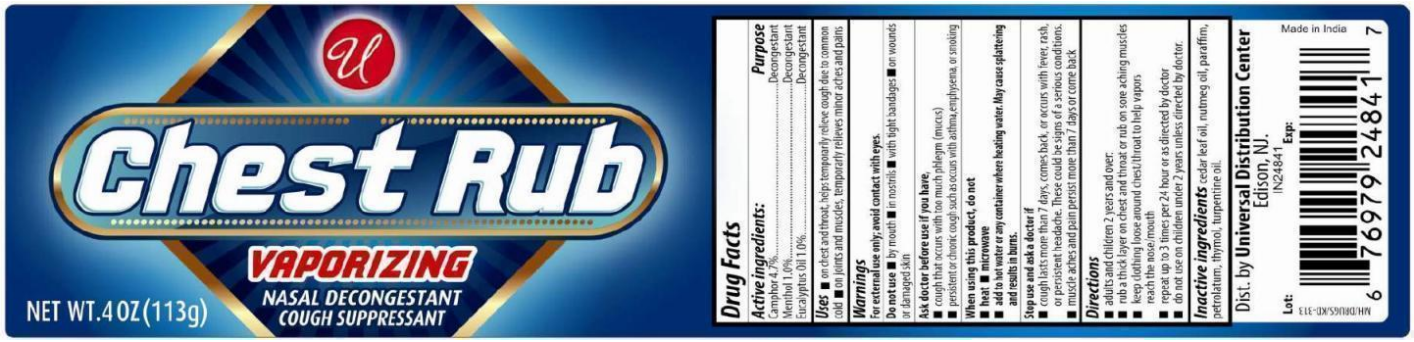
- adults and children 2 years and over
- rub a thick layer on chest and throat or rub on sore aching muscles
- keep clothing loose around chest/throat to help vapors reach the nose/mouth
- repeat up to 3 times per 24 hours or as directed by doctor
- do not use on children under 2 years unless directed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

Inactive ingredients

cedar 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:52000-012
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 g in 100 g
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1 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:52000-012-08	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2022	
2	NDC:52000-012-09	56.6 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2022	
3	NDC:52000-012-10	100 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2022	
4	NDC:52000-012-11	113 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2022	
5	NDC:52000-012-12	150 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2022	
6	NDC:52000-012-13	170 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2022	
7	NDC:52000-012-14	226 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/15/2013	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Anicare Pharmaceuticals Pvt. Ltd (916837425)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52000-012)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(52000-012)

Revised: 11/2022 Universal Distribution Center LLC