

MEDICATED CHEST RUB- camphor, menthol, eucalyptus oil cream
Orazen Inc

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.

Medicated chest rub

Active Ingredients	Purpose
Menthol 2.6%	Cough suppressant/Topical Analgesic
Camphor 4.8%	Cough suppressant/Topical Analgesic
Eucalyptus oil 1.2%	Cough Suppressant

Uses Temporarily relieves throat and chest

- cough
- nasal congestion due to common cold
- aching muscles
- minor aches and pains

Keep out of reach of children. In case of of accidental ingestion, get medical help or contact a Poison Control Center immediately.

Stop use and ask a doctor if

muscle aches/pains persist for more than 7 days or come back

cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition

Warnings

For external use only

Do not use

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

Ask a doctor before use if you have

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

- cough associated with smoking

When using this product do not

- heat

- microwave

- use near open flame

- add to hot water or any container where heating water may cause splattering and result in burns

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

Directions

- see important warnings under "When Using this product"

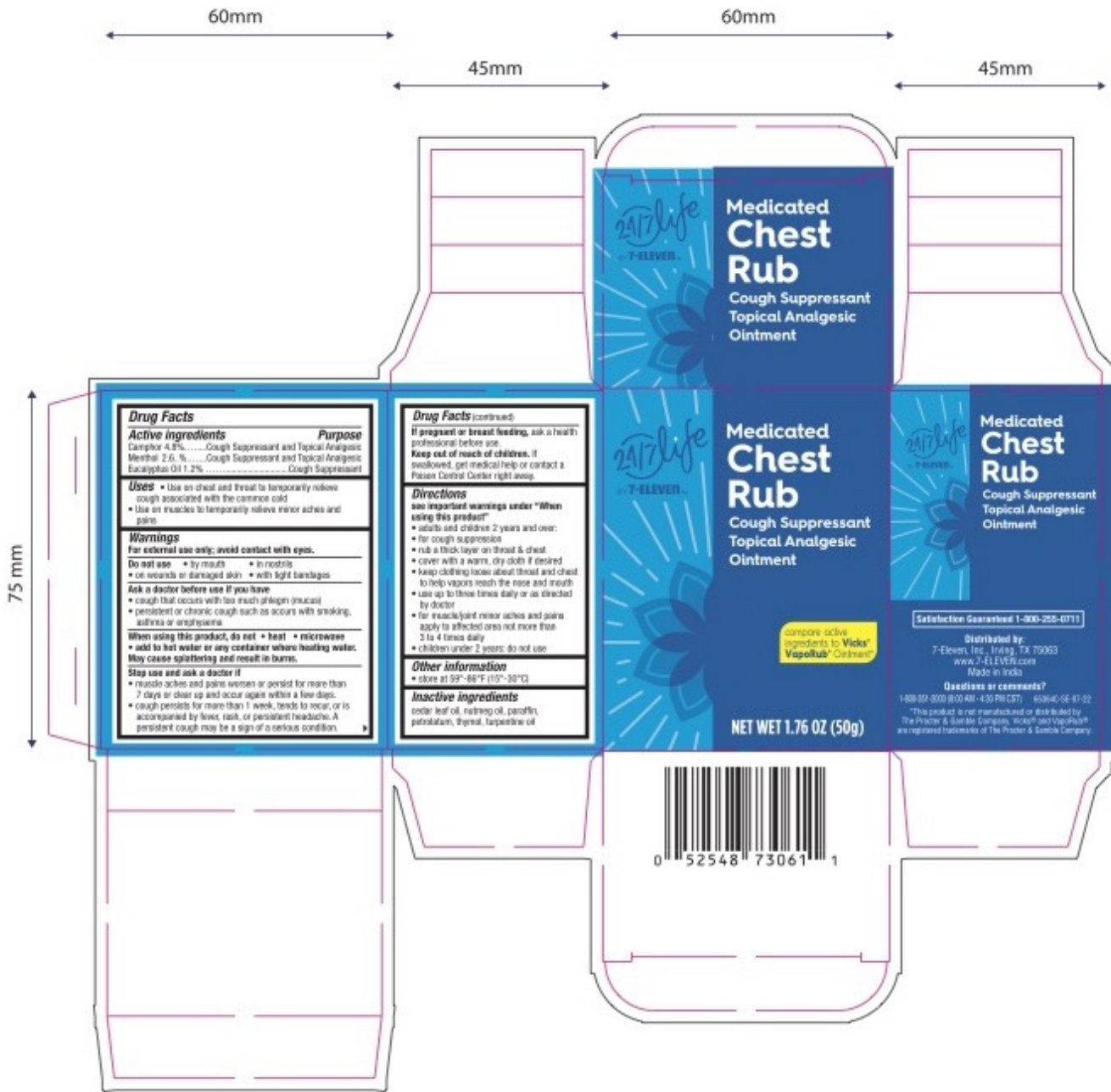
- children under 2 years of age, ask a doctor before using the product

- Adults and children 2 years and older. rub a thick layer of on chest and throat or rub on sore aching muscles. If desired cover with a dry soft cloth but keep clothing loose. Repeat up to 3 times daily

Other information Store at room temperature

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

medicated chest rub



MEDICATED CHEST RUB

camphor, menthol, eucalyptus oil cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71927-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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
EUCALYPTUS OIL (UNII: 2R04ONI662) (EUCALYPTUS OIL - UNII:2R04ONI662)	EUCALYPTUS OIL	1.2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CEDAR LEAF OIL (UNII: BJ169U4NLG)	
NUTMEG OIL (UNII: Z1CLM48948)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
THYMOL (UNII: 3J50XA376E)	
TURPENTINE (UNII: XJ6RUH004G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-020-01	50 g in 1 JAR; Type 0: Not a Combination Product	02/14/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/14/2022	

Labeler - Orazen Inc (080916640)

Registrant - Jell Pharmaceuticals Pvt Ltd. (726025211)

Establishment

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt Ltd.		726025211	manufacture(71927-020)

Revised: 11/2022

Orazen Inc