# ELIZABETH HEALTH STYLE CHESTRUB VAPORIZING ACTION- camphor (synthetic), levomenthol, eucalyptus ointment Singhfam Corporation

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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## Elizabeth Style Chest Rub

Active Ingredient	Purpose
Camphor 5.00%analgesic	Cough suppressant, nasal decongestant & topical
Menthol 2.60%analgesic	. Cough suppressant, nasal decongestant & topical
Eucalyptus Oil 1.20%analgesic	Cough suppressant, nasal decongestant & topical

#### Use

Temporarily relieves symptoms associated with the common cold:

- cough
- nasal congestion
- chest congestion

Temporarily relieves minor aches and pains of muscles.

# **Warnings**

# For external use only. Avoid contact with eyes. Ask a doctor before use if you have

- Cough with excessive phlegm (mucus)
- Chronic cough that lasts or 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.

- Muscle aches and 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 sign of a serious condition

**If pregnant or breast-feeding**, consult a physician before use.

**Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

## See important warnings under "Do not use this product".

- Children under 2 years of age, ask a doctor.
- Adults and children 2 years of age or older: Rub a thick layer on chest and throat. If desired, loosely cover with a soft dry cloth but keep clothing loose.
- Repeat up to 3 times daily, or as directed by a doctor.

# **Inactive ingredients**

BHT, Cedar Oil, Hard Wax, Light Liquid Paraffin, Micro Wax, Nutmeg Oil, Pine Oil, Thymol.

# Package Label - Principal Display Panel



#### **ELIZABETH HEALTH STYLE CHESTRUB VAPORIZING ACTION**

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52920-135
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	5 g in 100 g	
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	2.6 g in 100 g	
		1 2 0	

Inactive Ingredients			
Ingredient Name	Strength		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
CEDAR LEAF OIL (UNII: BJ169U4NLG)			
PARAFFIN (UNII: 1900E3H2ZE)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)			
NUTMEG OIL (UNII: Z1CLM48948)			
WHITE PINE OIL (UNII: HA5CX6676U)			
THYMOL (UNII: 3J50XA376E)			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:52920-135- 01	113 g in 1 DRUM; Type 0: Not a Combination Product	01/05/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/05/2023	

# Labeler - Singhfam Corporation (019499958)

# **Registrant -** Jell Pharmaceuticals Pvt Ltd. (726025211)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52920-135)	

Revised: 1/2023 Singhfam Corporation