CHEST RUB VAPORIZING ACTION- menthol and camphor and eucalyptus oil gel

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.

Chest Rub Vaporizing Action Gel

Active Ingredients

Camphor 4.8%

Menthol 2.6%

Eucalyptus Oil 1.2%

Purpose

Cough Suppressant

Nasal Decongestant

Topical Analgesic

Uses

Temporarily releives symptoms associated with the common cold:

- cough
- nasal congestion
- chest congestion

Temporarily relives minor aches and pains of muscles.

Warnings

For external use only. Avoid contact with eyes.

Ask a doctor before use if you have,

- · chronic cough that lasts or as occurs with smoking, asthma, or emphysema
- cough with excessive phlegm (mucus)

Do not use this product

- near an open flame
- by adding water
- by mouth
- in a microwave oven
- on wounds or damaged skin
- with tight bandages
- in nostrils
- added to hot water or any container where you are heating water
- may cause splattering and results in burns

Stop use and ask a doctor if:

- if 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 signs of a serious conditions
- if pregnant or breast-feeding, consult a physician before use.

Keep out of the 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

Petrolatum, Nutmeg Oil, Turpentine Oil, Cedar Leaf Oil, Thymol, Parrafin.

PRINCIPAL DISPLAY PANEL

CHEST RUB VAPORIZING ACTION GEL

NASAL DECONGESTANT AND COUGH SUPPRESSANT

NET WT. 4 OZ (113g)



CHEST RUB VAPORIZING ACTION

menthol and camphor and eucalyptus oil gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52920-133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	4.8 g in 100 g	

26~

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	∠.o 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			
PETROLATUM (UNII: 4T6H12BN9U)				
NUTMEG OIL (UNII: Z1CLM48948)				
TURPENTINE OIL (UNII: C5H0QJ6V7F)				
CEDAR LEAF OIL (UNII: BJ169U4NLG)				
THYMOL (UNII: 3J50XA376E)				
PARAFFIN (UNII: 1900E3H2ZE)				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:52920- 133-48	113 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/21/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/10/2015	

Labeler - Singhfam Corporation (019499958)

Registrant - Jell Pharmaceuticals Pvt. Ltd. (726025211)

Establishment				
Name	Address	ID/FEI	Business Operations	
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52920-133)	

Revised: 11/2022 Singhfam Corporation